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Study on Veterans Affairs (VA) Extramural Funding

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Executive Summary

Purpose and Background

In 1988, the Department of Veterans Affairs (VA), in accordance with Public Law (P.L.) 100-322 [now codified at sections 7361-66 of title 38, United States Code (U.S.C.)], authorized the establishment of VA-affiliated nonprofit research and education corporations (NPCs) to be located near VA medical centers (VAMCs). These private, state-chartered nonprofit entities were established to provide flexible mechanisms for the administration of funds other than those appropriated to VA for the conduct of VA-approved research. Throughout this report, we refer to these funds as "extramural" since they are not part of VA appropriations. Congress later expanded the NPCs' purview to include support for VA education and training activities. The fundamental purpose of NPCs is to serve Veterans by supporting VA research and education to improve the quality of care that Veterans receive.[1]

There are 83 independent 501(c) (3) NPCs located in 44 states, Puerto Rico, and Washington D.C. NPCs have made substantial contributions to VA research and education. Combined NPC revenues in 2016 were more than $266 million.[2] To date, there have been no systematic efforts to examine the administrative and funding distribution mechanisms specific to NPCs.

VAMCs and their academic affiliates (medical schools, universities) have a long history of collocation and collaboration predating the establishment of NPCs. Many researchers employed at the VA also have an academic appointment at the affiliated medical school and university. To standardize terminology used in this report, we refer to these researchers as "dual appointed VA investigators" or "VA principal investigators" (PIs). We recognize that many, if not most, dual appointed VA investigators are also university faculty and that affiliates may not use or recognize the term "VA PI." We use the term for convenience in this report, and it also includes VA researchers who may have no academic appointment. VA researchers, with or without an academic appointment, frequently apply for funding from extramural sources, such as other federal agencies,

[1] VAs and NPCs: A Unique Public/Private Partnership. https://navref.wildapricot.org/VA-and-NPCs-A-Unique-Public-Private-Partnership. Accessed 09/11/18.

[2] Department of Veterans Affairs (2017). *2016 Annual Report of Nonprofit Research and Education Corporations (NPC).*

including the National Institutes of Health (NIH) or the Department of Defense (DOD), from private industry, or from foundations and non-profit agencies such as the American Cancer Society.[3] VA researchers may conduct extramurally funded projects at the VAMC and/or the affiliate, and the funds may be administered by the affiliate or the NPC, or both, through the use of subawards. A subaward is a mechanism similar to a subcontract, in which the organization awarded the grant (i.e., the prime) commits a portion of the funding to the subawardee in exchange for management and performance of a share of the work.

The objective of the current study is to assess how the NPCs and affiliates meet the needs of VA, and to determine areas that can be strengthened to improve research productivity and quality to benefit VA and Veterans' health. This report provides a broad and comprehensive understanding about the administration of extramural research funds; how stakeholders report making grant submission and administration decisions; the relative benefits and shortcomings stakeholders attribute to the academic affiliates and the NPCs in facilitating VA research and education; and how stakeholders believe the administration of extramural funds benefits Veterans and the mission of VA.

Specifically, the VA Office of Research and Development (ORD) tasked Westat with gathering the answers to the following questions:

1. What is the purpose of the VA NPCs?
    a. Please provide summaries from the statute and VHA Handbooks to clearly define how NPCs are to be utilized.
    b. Are the VA NPCs being utilized to their fullest potential?
2. Who makes the decision as to where a grant will be administered?
    a. What is the local VA policy for the administration of a federal grant involving one of its employees?
3. How are the NIH grant funds administered?
    a. If the majority of the work (i.e., greater than 50%) is done at the VA, does the NPC administer the funding?

[3] Veterans Health Administration. (n.d.) *The Report of the Blue Ribbon Panel on VA-Medical School Affiliations: Transforming an Historic Partnership for the 21st Century*. VHA: Office of Academic Affiliations.

4. How much research supported by NIH grants is being conducted solely at the VAMC, and how much is spent in collaboration with the university?

5. How many of the NIH-granted funds are spent solely at the VA?

    a. How much is spent in collaboration with the university?

    b. Is the NPC a subcontractor on work done at the VA?

6. When funding is received at the university, where is the research being conducted?

    a. What kinds of research are being conducted?

    b. How many of the research projects conducted at the university use a majority of Veterans as subjects?

7. Is there a policy directing VA investigators with dual university appointments which institution should serve as the grant institution?

8. What is the academic affiliate's policy for the administration of a federal grant involving one of its employees when the research is being performed at the VA?

    a. Do the academic affiliates comply with all VA regulations and policies?

    b. Are they held to the same standards as the VA NPCs?

    c. Do these two policies conflict with one another?

    d. Does it cause a conflict for the employee?

    e. Who manages or resolves this conflict?

9. How does VA benefit when federal grants are administered by the local academic affiliate?

    a. How does the academic affiliate use the indirect fee to benefit VA?

10. What support does the NPC and the university provide to the investigators who submit grants to NIH or other Federal agencies?

11. Does the nonprofit corporation have an explicit education mission in its bylaws? YES or NO

12. Does the nonprofit corporation have the Associate Chief of Staff for Education as a statutory board member? YES or NO

13. What percent of grants/contracts are explicitly for education activities?

Methods

To address and answer the study questions, we employed mixed methods, including statistical analysis of administrative data and thematic analysis of in-depth interviews. Some of the research questions were quantitative, involving numbers of grants or quantity of revenue. For example, Question 4 above, "How much research supported by NIH grants is being conducted solely at the VAMC, and how much is spent in collaboration with the university?" required compiling NIH grant information as entered in VA's Research and Development Information System (RDIS). In contrast, Question 2 above, "Who makes the decision as to where a grant will be administered?" necessitated discussions with individuals at the VA Medical Centers (VAMCs) and the NPCs about how decisions are made regarding whether the academic affiliate or the nonprofit corporation will serve as the prime on the grant.

Data Sources

Our mixed-methods approach to the study utilizes four sources of data:

1. **The Research and Development Information System (RDIS),** the database for budgetary and project data pertaining to the VA Research and Development Program;
2. **2014, 2015, and 2016 Annual Reports** of the Department of Veterans Affairs Nonprofit Research and Education Corporations (NPCs) with Appendices;
3. **Case studies** of the extramural ecosystem at selected VAMCs; and
4. **In-depth interviews** of NPC Executive Directors and VA Medical Center Associate Chiefs of Staff (ACOSs) for Research and Development.

Data Collection and Analysis

Data collection for answering the quantitative research questions (3a, 4, 5, 5a, 6, 6a, and 6b) relied on the information within the RDIS data system. Westat used the 2014-2016 *Annual Reports of the VA NPCs* to calculate relative expenditures on education and research to answer research question 13.

Qualitative data collection involved 146 in-depth interviews with 72 Executive Directors of NPCs and 74 Associate Chiefs of Staff for Research (ACOS-Rs) of the VAMCs affiliated with the NPCs. Westat sought to interview all 83 EDs and 83 ACOS-Rs. Twelve (12) individuals did not respond to

multiple emails and phone calls inviting them to participate. Two (2) individuals refused our invitation for an interview, two (2) others were unavailable, and three (3) ED or ACOS-R posts were vacant.

Interviews were semi-structured so interviewees could explain what they experienced as the most important successes and challenges involving the administration of extramural grants for VA research. With interviewee permission, Westat recorded and transcribed interviews. Interview transcriptions were imported into NVivo, a Computer Assisted Qualitative Data Analysis Software program to facilitate analysis and writing.

Data collection was reviewed and approved by Westat's Institutional Review Board (IRB). Westat received IRB exemption on January 28, 2018.

Results

Q1. What is the purpose of the VA NPCs?

Q1a. Please provide summaries from the statute and VHA Handbooks to clearly define how NPCs are to be utilized.

The purpose of the NPCs is to facilitate VA research and education that will enhance health care provided to Veterans. NPCs are private, state-chartered nonprofit entities established to provide flexible mechanisms for the administration of funds other than those appropriated to VA for the conduct of VA-approved research. NPCs make it possible for VA researchers to apply for and utilize this extramural funding, thereby increasing VA's overall research capacity. Extramural funding sources include other federal agencies such as the National Institutes of Health (NIH) and the Department of Defense (DOD), as well as funding from industry and non-profit organizations that support and sponsor health research and clinical trials.

Q1b. Are the NPCs being utilized to their fullest potential?

The majority of ACOSs and EDs did not believe their NPC was being utilized to its fullest potential. About a quarter of ACOSs and EDs did believe their NPC was being utilized to its fullest potential.

Those interviewees who thought their NPC was not used to its fullest potential gave the following reasons:

- A lack of staffing and administrative infrastructure at NPCs relative to affiliates;
- Insufficient NPC visibility and promotion;
- Insufficient incentives and supports for dual appointed VA PIs to run grants through the NPCs; and in contrast,
- Strong incentives for, and pressure on, dual appointed VA PIs to submit grants through their academic affiliate.

Q2. Who makes the decision as to where a grant will be administered?

Q2a. What is the local VA policy for the administration of a federal grant involving one of its employees?

Q7. Is there a policy directing VA investigators with dual appointments which institution should serve as the grant institution?

Research questions 2, 2(a) and 7 focus on the topic of how decisions are made regarding where grants led by VA-employed investigators will be managed, and what policies, if any, influence or determine this decision. Because these are related questions, they were addressed together. Based on interview data with 146 ACOSs and EDs at 78 VAMCs/NPCs, we found that:

- There is no single policy across VAMCs that addresses the issue of where VA investigator grants should be managed, and under what conditions. EDs of NPCs and ACOS-Rs described a range of approaches regarding how the VAMC deals with grant administration decisions.
- VAMCs fall into one of three groups with respect to extramural grant submission policies:
  - Group 1: VAMCs with formal written policies (23 of 78);
  - Group 2: VAMCs with unwritten informal guidelines (20 of 78); and
  - Group 3: VAMCs that lack a written policy or informal guidelines and at which PIs decide. (35 of 78).
- The most common policy criterion in use among VAMCs with a written policy was the "preponderance rule." This rule designates the NPC as the appropriate organization

through which a PI should submit a grant if the majority of work will be performed at VA. Exceptions require review and authorization by a person or committee providing oversight for the VAMC.

- Some VAMCs with formal written policies have established a Memorandum of Understanding (MOU) with their academic affiliate.
- VAMCs with informal guidelines most commonly used some version of the preponderance rule as the basis of their grant submission guidelines.
- Several sites have policies or guidelines that specify that NIH grants, or sometimes all federal grants, will be administered by the academic affiliate.
- NPCs associated with VAMCs that have formal written policies are larger and have higher revenue, on average. The 23 NPCs in this group reported $162.4 million in revenue in 2016, or approximately 62 percent of the revenue reported for all 83 NPCs in 2016.

Q3. How are NIH grant funds administered?

Q3a. If the majority of the work (i.e., greater than 50 percent) is done at the VA, does the NPC administer the funding?

During 2014-2016, VA investigators worked on an average of 1467 NIH grants per year. NPCs administered slightly more than one-third of these grants. Academic affiliates managed the rest. VA PIs reported expending $337.5 million in NIH grant funding in 2014, $297.5 million in 2015 and $280.3 million in 2016. NPCs managed between 27 and 29 percent of this funding, depending on the year. Academic affiliates managed the remainder.

- Between 2014 and 2016, NPCs collectively increased their share of NIH prime funding for grants that were performed predominately at VA. The share of this funding managed by NPCs rose from 46.8 percent in 2014 to 55.6 percent in 2016.
- This increase in the NPCs' share of prime funding relative to academic affiliates has taken place at the same time in which the overall amount of NIH funding expended for VA extramural research declined substantially. The increase in the NPCs' share of prime funding is not due to an increase in their NIH revenue, but rather to a significant decline in NIH funding managed by the affiliates for work performed predominately at VA.

- The 13 largest NPCs—those with more than $4 million in 2016 revenue—administer a disproportionate share of all the NIH funding managed by NPCs. NPCs in this largest size category administered roughly 90 percent of the NIH prime funding under management by all the NPCs during 2014-2016.

- For the 70 NPCs with revenues less than $4 million, the academic affiliates are much more likely to administer the NIH grants of VA investigators, even if most or all the work is performed at VA.

Q4. How much research supported by NIH is conducted solely at the VA, and how much is spent in collaboration at the university?

Q5. How many of the NIH-granted funds are spent solely at the VA?

Q5a. How much is spent in collaboration with the university?

Questions 4, 5 and 5(a) have a similar focus. Therefore, we present the findings collectively.

- Slightly less than half of NIH grants performed by VA investigators are for projects where work is conducted solely at VA. The share, by year, of NIH grants performed solely at VA was 50 percent in 2014, 48 percent in 2015 and 48 percent in 2016.

- Between 2014 and 2016, there was an overall decrease in the total number of NIH grants performed by VA investigators. During this period, the share of grants performed in collaboration with academic affiliates increased slightly, from 50 percent in 2014 to 52 percent in 2016.

- NIH grants where work is conducted solely at VA are concentrated at locations that host the largest NPCs (i.e., those with more than $4 million in 2016 revenue). Approximately 28 percent of all NIH funded grants conducted solely at VA were performed at these 13 locations.

- For VAMCs that host an NPC with less than $4 million in revenue, it is much more common for grants to be performed in collaboration with the affiliate rather than exclusively at VA.

- Most NIH funding expended by VA investigators is spent on grants performed collaboratively (i.e., where less than 100 percent of the work is performed at VA). The share

of expenditures for collaborative projects, as compared to projects conducted solely as VA, increased from 53 percent in 2014 to 59 percent in 2016.

Q5b. Is the NPC a subcontractor on work done at the VA?

A majority of interviewees explained that when the academic affiliate manages the grant of a dual appointed VA investigator, and some or all of the work is performed at the VA, the NPC is provided a subaward to cover the costs of the work performed at VA. At roughly one-third of VAMCs/NPCs however, interviewees noted that the affiliate, when acting as prime, does not consistently provide subawards to the NPC even when the work is conducted at the VA. At some VAMCs/NPCs where subawards are not consistently provided for work conducted at the VA, the affiliate and the VAMC have an alternate arrangement—such as a lump sum payment—to recapture some of the costs associated with grant performance.

Q6. When funding is received at the university, where is the research conducted?

Based on RDIS data from 2014-2016, the majority of grants administered by academic affiliates on behalf of VA investigators support projects that are conducted collaboratively; that is, conducted at both VA and the affiliate. For most affiliate-managed projects, the preponderance of work (more than 50%) does not occur at the VA. However, a sizable share (between 42% and 45%, depending on the year) of affiliate-managed grants does fund work conducted mostly or fully at VA.

There is variation in where the work is conducted when the university manages a VA investigator's grant, based on the size of the NPC. At locations that host the largest NPCs by revenue, affiliate-managed grants tend to support projects in which the preponderance of work is conducted at VA. At all other locations (i.e., those hosting NPCs not in the largest size category), affiliate-managed grants tend to support projects in which the preponderance of work does not occur at VA.

Q6a. What kinds of research are conducted?

Although academic affiliates manage extramural research funds from multiple sources, NIH funded two-thirds of all affiliate-managed grants in 2014, 2015 and 2016. The kinds of research supported by affiliate-managed grants span a wide range of health issues and diseases that affect the 9 million+ Veteran beneficiaries served by VA healthcare. There are more than 1800 keyword descriptions used by VA investigators to describe the subject matter of their research grants. Frequently listed research topics in the RDIS database include cancer, injuries, diabetes, heart and kidney disease, alcohol dependence and brain function.

Q6b. How many of the research projects conducted at the university use a majority of Veterans as subjects?

RDIS does not contain a specific designation for projects that utilize a majority of Veterans as subjects. However, PIs are required to note in RDIS if their project involves human subjects, and to indicate the percentage of their research expenditures that take place at VA. Based on an analysis of these variables, we estimate that, over the three-year period from 2014 to 2016, slightly less than one-fourth (23.6 percent) of research projects managed by the university used a majority of Veterans as subjects.

Q8. What are academic affiliates' policies for the administration of a federal grant involving one of its employees when the research is performed at the VA?

- **Q8a. Do the academic affiliates comply with all VA regulations and policies?**
- **Q8b. Are they held to the same standards as the VA NPCs?**
- **Q8c. Do these policies conflict with each other?**
- **Q8d. Does it cause a conflict for the employee?**
- **Q8e. Who manages the conflict?**

ACOSs had mixed views on the question of whether VA research policies and procedures differ from those of the affiliate, but the majority said that policies were similar and were not in conflict. Both affiliate and VA policies integrate scientifically accepted standards and practices for research. ACOSs explained that both the NPC and the affiliate are required to abide by applicable VA regulations and policies when administering grants performed fully or in part at VA, and they are both required to comply with regulations stipulated by the funding agency (e.g., NIH).

Many interviewees noted that the regulatory environment of VA is more stringent than that of the university, but ACOSs generally did not interpret VA's unique administrative requirements as a fundamental difference in research policy or practice between the affiliate and VA.

Interviewees told us that affiliates work in collaboration with the VA to maintain VA's standards and regulations when dual appointed VA staff are conducting collaborative projects with the affiliate. Many ACOSs were complimentary of their affiliate's efforts to incorporate VA-specific procedures.

Most ACOSs did not believe employees experience serious conflict due to different research policies between the VA and the affiliate. Several ACOSs explained that conflict is avoided by ensuring that the affiliate and PIs are aware of and comply with VA regulations applicable to collaborative research. VA representation on joint or affiliate-led IRBs is one way that VAMCs achieve this goal.

A minority of interviewees said that research policies and procedures between the affiliate and the VA are different in some ways, with most noting that VA data security procedures and policies related to privacy/data sharing were much more stringent or burdensome compared with the affiliate. Some ACOSs cited examples in which they felt VA's regulations and procedures in this area posed a barrier to collaborative research.

Q9. How does the VA benefit when federal grants are administered by the local academic affiliate?

When asked how the VA benefits when the academic affiliate administers federal grants, most ACOSs (who are generally also dual appointed PIs) described how the affiliates' services and resources strengthen VA research. The services and resources they described included:

- Laboratory space and equipment;
- Access to core laboratories, animal facilities, etc., on campus;
- Computing and library resources;
- Compliance infrastructure;
- Scientific and intellectual community and continuing education;
- Assistance with attracting, recruiting, and retaining the best researchers; and
- Salary support for workweeks exceeding 40 hours.

Q9a. How does the academic affiliate use the indirect fee to benefit VA?

The majority of interviewees reported that the affiliate does not use the indirect fee to benefit the VA. About one-third of interviewees explained that the affiliate uses the indirect fee to pay for resources at the university that benefit the research enterprise of VA by helping to support the work of dual appointed PIs.

Q10. What support does the university and the NPC provide to VA investigators submitting federal grants?

We discuss the support that the university provides to VA investigators in Question 9 above. EDs and ACOS reported that NPCs further the aims of research to improve Veterans' health by:

- Quickly hiring research support staff (research assistants, project managers, etc.) to serve on dual-appointed VA PIs' extramural projects;

- Purchasing equipment and materials for extramural VA research;
- Supporting VA's education mission with funds for travel to scientific meetings;
- Organizing research events;
- Increasing opportunities for Veterans to participate in clinical trials; and
- Providing pre- and post-award grant administration services with more personal attention and friendly customer service.

Q11. Does the nonprofit corporation have an explicit education mission in its bylaws? YES or NO?

Ninety-three percent of NPC Executive Directors who were asked this question (66 of 71) reported that their NPC has an explicit education mission in its bylaws. Five Executive Directors said their NPC does not.

Q12. Does the nonprofit corporation have the Associate Chief of Staff for Education as a statutory board member?

Ninety-four percent of NPC Executive Directors who were asked this question (67 of 71) reported that their NPC has the Associate Chief of Staff for Education as a statutory board member. Four Executive Directors said their NPC does not.

Q13. What percent of grants and contracts are explicitly for education activities?

In 2014, education expenses represented about one-half of 1 percent of the $230.5 million expended by NPCs on research and education. The share of spending on education relative to research, while still relatively small, more than doubled during 2015. In 2015, education spending represented 1.5 percent of the $232.5 million spent by NPCs on both research and education. In 2016, education expenditures were 1.4 percent of the $229 million expended on both missions.

1. Purpose and Background

In 1988, the Department of Veterans Affairs (VA), in accordance with Public Law (P.L.) 100-322 [now codified at sections 7361-66 of title 38, United States Code (U.S.C.)], authorized the establishment of VA-affiliated nonprofit research and education corporations (NPCs) to be located near VA medical centers (VAMCs). These private, state-chartered nonprofit entities were established to provide flexible mechanisms for the administration of funds other than those appropriated to VA for the conduct of VA-approved research. Throughout this report, we refer to these funds as "extramural" since they are not part of VA appropriations. Congress later expanded the NPCs' purview to include support for VA education and training activities. The fundamental purpose of NPCs is to serve Veterans by supporting VA research and education to improve the quality of care that Veterans receive.[4]

There are 83 independent 501(c) (3) NPCs located in 44 states, Puerto Rico, and Washington D.C. NPCs have made substantial contributions to VA research and education. Combined NPC revenues in 2016 were more than $266 million.[5] To date, there have been no systematic efforts to examine the administrative and funding distribution mechanisms specific to NPCs.

VAMCs and their academic affiliates (medical schools, universities) have a long history of collocation and collaboration predating the establishment of NPCs. Many researchers employed at the VA also have an academic appointment at the affiliated medical school and university. To standardize terminology used in this report, we refer to these researchers as "dual appointed VA investigators" or "VA principal investigators" (PIs). We recognize that many, if not most, dual appointed VA investigators are also university faculty and that affiliates may not use or recognize the term "VA PI." We use the term for convenience in this report, and it also includes VA researchers who may have no academic appointment. VA researchers, with or without an academic appointment, frequently apply for funding from extramural sources, such as other federal agencies, including the National Institutes of Health (NIH), or the Department of Defense (DOD), from

[4] VAs and NPCs: A Unique Public/Private Partnership. https://navref.wildapricot.org/VA-and-NPCs-A-Unique-Public-Private-Partnership. Accessed 09/11/18.

[5] Department of Veterans Affairs (2017). *2016 Annual Report of Nonprofit Research and Education Corporations (NPC).*

private industry, or from foundations and non-profit agencies such as the American Cancer Society.[6] VA researchers may conduct extramurally funded projects at the VAMC and/or the affiliate, and the funds may be administered by the affiliate or the NPC, or both, through the use of subawards. A subaward is a mechanism similar to a subcontract, in which the organization awarded the grant (i.e., the prime) commits a portion of the funding to the subawardee in exchange for management and performance of a share of the work.

The objective of the current study is to assess how the NPCs and affiliates meet the needs of VA, and to determine areas that can be strengthened to improve the overall quality and productivity in conducting research and building VA capacity to benefit Veterans' health. This report provides a broad and comprehensive understanding about the administration of extramural research funds; how stakeholders report making decisions regarding grant submission and administration of extramural funding—including the policies that guide these decisions; the extent to which stakeholders have a preference for the academic affiliate or the NPC for grants management, and the perceived benefits and shortcomings of each; and how stakeholders think the administration of extramural funds may benefit the mission of the VA.

[6] Veterans Health Administration. (n.d.) *The Report of the Blue Ribbon Panel on VA-Medical School Affiliations: Transforming an Historic Partnership for the 21st Century*. VHA: Office of Academic Affiliations.

2. Methods

In this chapter, we present an overview of our approach to fulfilling the aims of the Study on Veterans Affairs (VA) Extramural Funding. We describe the scope of the study, the research plan and rationale, and the data sources and protocols utilized to answer the research questions.

2.1 Study Plan

The Department of Veterans Affairs Office of Research and Development (ORD) tasked Westat with answering the following questions:

1. What is the purpose of the VA NPCs?
    a. Please provide summaries from the statute and VHA Handbooks to clearly define how NPCs are to be utilized.
    b. Are the VA NPCs being utilized to their fullest potential?
2. Who makes the decision as to where a grant will be administered?
    a. What is the VAMC policy for the administration of a federal grant involving one of its employees?
3. How are the NIH grant funds administered?
    a. If the majority of the work (i.e., greater than 50%) is done at the VA, does the NPC administer the funding?
4. How much research supported by NIH grants is being conducted solely at the VAMC, and how much is spent in collaboration with the university?
5. How many of the NIH-granted funds are spent solely at the VA?
    a. How much is spent in collaboration with the university?
    b. Is the NPC a subcontractor on work done at the VA?

6. When funding is received at the university, where is the research being conducted?

    a. What kinds of research are being conducted?

    b. How many of the research projects conducted at the university use a majority of Veterans as subjects?

7. Is there a policy directing VA investigators with dual university appointments which institution should serve as the grant institution?

8. What is the academic affiliate's policy for the administration of a federal grant involving one of its employees when the research is being performed at the VA?

    a. Do the academic affiliates comply with all VA regulations and policies?

    b. Are they held to the same standards as the VA NPCs?

    c. Do these two policies conflict with one another?

    d. Does it cause a conflict for the employee?

    e. Who manages or resolves this conflict?

9. How does VA benefit when federal grants are administered by the local academic affiliate?

    a. How does the academic affiliate use the indirect fee to benefit VA?

10. What support does the NPC and the university provide to the investigators who submit grants to NIH or other Federal agencies?

11. Does the nonprofit corporation have an explicit education mission in its bylaws? YES or NO

12. Does the nonprofit corporation have the Associate Chief of Staff for Education as a statutory board member? YES or NO

13. What percent of grants/contracts are explicitly for education activities?

To address and answer the study questions, we employed mixed methods, including statistical analysis of administrative data and thematic analysis of in-depth interviews. Some of the research questions were quantitative, involving numbers of grants or quantity of revenue. For example, Q4 above, "How much research supported by NIH grants is being conducted solely at the VAMC, and how much is spent in collaboration with the university?" required compiling NIH grant information as entered in the VA's Research and Development Information System (RDIS) database. In contrast, Q2 above, "Who makes the decision as to where a grant will be administered?"

necessitated discussions with individuals at the VAMCs and the NPCs about how they decide whether the academic affiliate or the non-profit corporation will serve as the prime on the grant. This question required qualitative data collection and analysis.

Our mixed-methods approach to the study utilized four sources of data:

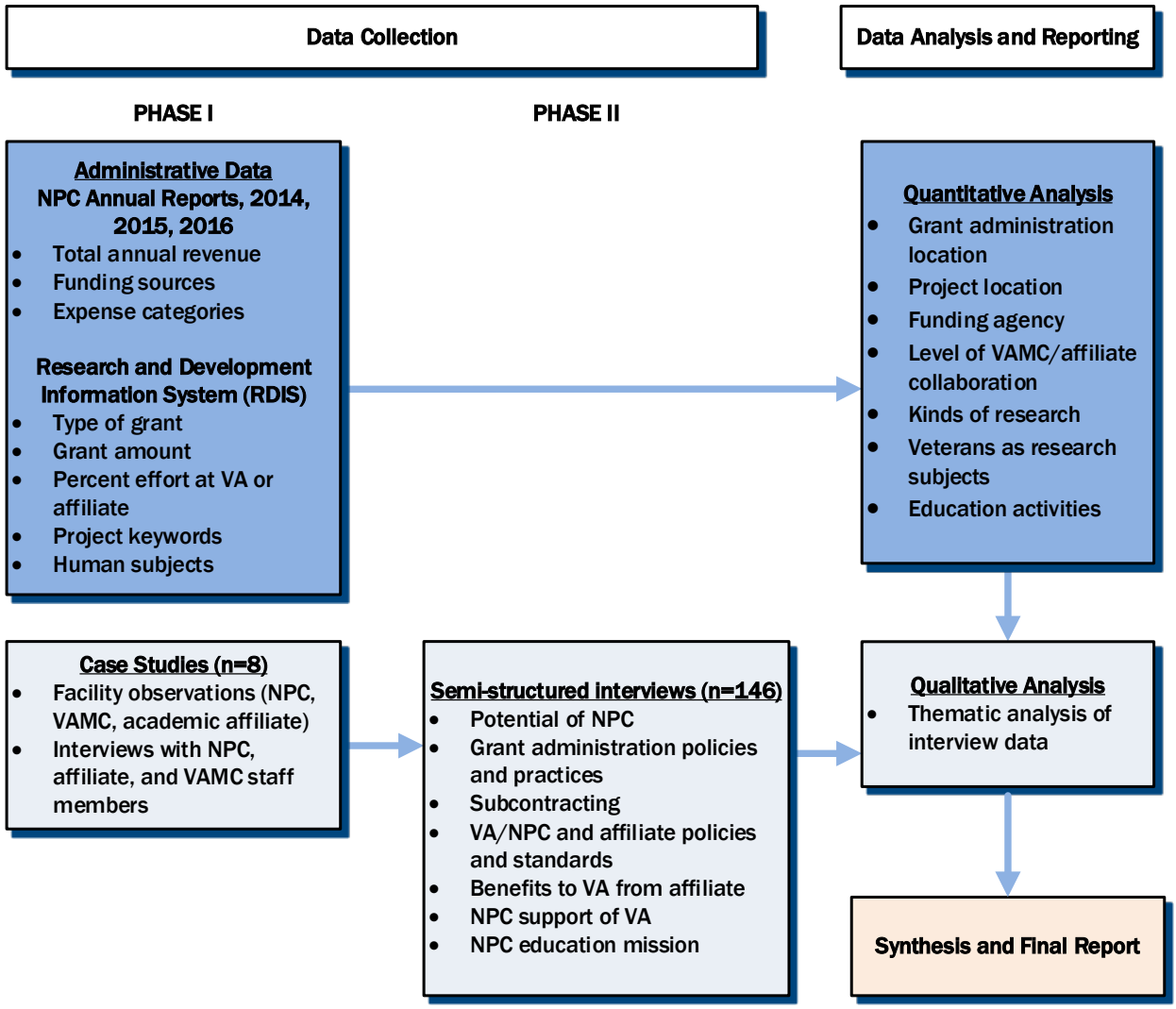
1. **The Research and Development Information System (RDIS),** the database for budgetary and project data pertaining to VA's Research and Development Program,
2. **2014, 2015, and 2016 Annual Reports** of the Department of Veterans Affairs Nonprofit Research and Education Corporations (NPCs) with Appendices,
3. **Case studies** of the extramural ecosystem at selected VAMCs, and
4. **In-depth interviews** of NPC Executive Directors and VA Medical Center (VAMC) Associate Chiefs of Staff (ACOSs) for Research and Development (R&D).

Our study design relied on three phases of data collection, as diagramed in Figure 2-1. The first phase of data collection required obtaining NPC Annual Reports from 2014, 2015, and 2016, and RDIS data for the same years.[7] We also conducted eight case studies to obtain in-depth information about grant administration policies and procedures at VAMCs and NPCs of various sizes and geographic locations. For each case study, we spoke with a range of stakeholders, including NPC Executive Directors (EDs), ACOS-Rs, dual appointed VA PIs, and staff at affiliates involved in administering dual appointed VA PIs' extramural research. In the second phase we conducted in-depth interviews with EDs and ACOS-Rs from nearly all remaining 75 sites not selected for the case studies. In total, interview data were collected from 146 EDs and ACOSs nationwide. At a small number of locations, we attempted but were unable to schedule an interview with a given ED or ACOS. A distribution of attempted and completed interviews of EDs and ACOSs is provided in Table 2.1 later in this chapter.

We used the interview data collected from the case studies and in-depth interviews to answer the qualitative research questions. Once we completed data collection, we conducted statistical analysis of the quantitative data and qualitative analysis of interview data. This report presents the integrated findings addressing the full set of research questions.

[7] 2016 was the latest year for which RDIS data were available for use in the study.

Figure 2-1. VA extramural funding study research design



2.2 Administrative Data Collection and Analysis

The following research questions required quantitative data analysis:

3. How are the NIH grant funds administered?
   a. If the majority of the work (i.e., greater than 50 percent) is done at the VA, does the NPC administer the funding?
4. How much research supported by NIH grants is being conducted solely at the VAMC, and how much is spent in collaboration with the university?
5. How many of the NIH-granted funds are spent solely at the VA?
   a. How much is spent in collaboration with the university?
6. When funding is received at the university, where is the research being conducted?
   a. What kinds of research are being conducted?
   b. How many of the research projects conducted at the university use a majority of Veterans as subjects?
13. What percent of grants/contracts are explicitly for education activities?

2.2.1 Data Sources

Westat utilized two sources of quantitative data to provide answers to the research questions in the box above. The first was financial data collected for the 2014, 2015, and 2016 *NPC Annual Reports*. [8] These data provide aggregates of all revenue received at each NPC, and expenses for education versus research. Financial tables list the amount of funding over $25,000 from each non-governmental and government funding source, including the National Institutes of Health (NIH) and the Department of Defense (DOD).

Using the financial data provided in the Annual Reports and companion financial tables, we were able to calculate the relative expenditures on education and research to answer, for example, Question 13: "What percent of grants/contracts are explicitly for education activities?"

[8] These three reports were the most recent available at the beginning of data analysis. They may be accessed at https://www.research.va.gov/programs/nppo/annual_report.cfm.

The second data source is the Research and Development Information System (RDIS) database. RDIS is the VA Central Office budgetary and project data repository for the VA's research program. It contains information on VAMC investigators, project allocations and expenditures, project abstracts, progress reports, and site of research.[9]

Individual VA PIs are responsible for inputting data on each project they hold on a yearly basis into RDIS. The VA Office of Research and Development does not validate the accuracy of PIs' reporting, but RDIS is the best available data source to address many of the study's research questions because it provides detailed information on grant expenditures by individual VA investigators. Within RDIS, a single research project can span multiple years, can be funded by a single grant spanning multiple years, or by multiple grants from separate funders, and can involve a single PI or multiple PIs. In subsequent chapters our analysis focuses on grants entered by investigators for three distinct calendar years—2014, 2015, and 2016—the most recent years for which data were available.

2.2.2 Data Analysis

To provide answers for Questions 3a, 4, 5, 5a, 6, 6a, and 6b, Westat utilized the RDIS data system. For the purpose of analysis, Westat considers a grant to refer to a single instance in which a PI receives extramural funding. A single grant may not necessarily represent an entire research project (for example, NIH and a private foundation may fund a single project by issuing two separate grants). Co-PIs who each receive funding for the same project are counted as separate grants, since each has a separate entry in RDIS.

In all analyses using RDIS, we refer to an "investigator-grant" as an instance in which a grant funds a PI's project. A funder may support multiple PIs for the same project, but because funding amounts are recorded at the PI level, each such case is counted as a separate grant for this report. Individual PIs may also have grants from multiple funders to support the same research project. RDIS data were used to answer the majority of the quantitative research questions, such as Question 4: "How much research supported by NIH grants is being conducted solely at the VAMC and how much is spent in collaboration with the university?"

[9] https://catalog.data.gov/dataset/research-and-development-information-system-rdis, accessed September 9, 2018.

Types of Research Projects of Dual Appointed VA PIs

Question 6a asks about the kinds of research conducted when the academic affiliate (that is, the university or university medical school) is the prime recipient and administrator of the grant. To analyze the types of research conducted, we examined the keywords associated with the projects administered by the affiliate. Keywords are descriptors PIs entered into the RDIS database to describe their project, such as "Vitamin D," or "skin." PIs are able to enter up to five keywords; however, a keyword could include short phrases, such as "clinical trial."

To assess patterns among the types of research conducted by dual appointed VA PIs, Westat analyzed keywords at the stem level. This was necessary since PIs entered similar keywords that will show as distinct in an automatic compilation, such as "alcohol," and "alcoholism." Therefore, we analyzed words at the stem level. For example, we coded the words "alcohol" and "alcoholism" as the same keyword. In contrast, "prostate cancer" was counted once in the "prostate" keyword group, and once again in the "cancer" keyword group. Table 3-12 presents the 20 most common keywords we extracted from RDIS.[10]

Number of Projects with Veterans as Research Subjects

Question 6b asks how many projects that take place at the academic affiliate use a majority of Veterans as research subjects. Many projects do not involve human subjects at all; instead, they rely on animals, medical records, or other administrative data. However, RDIS allows PIs to select "human use" to characterize their projects. To answer this research question, we made the assumption that projects coded as "human use" involved human research subjects. RDIS also contains project-level information on the share of work performed at the VA, and where the grant was administered. We made the additional assumption that when a "human use" project was being performed mostly or completely at VA, then the project used a majority of Veterans as subjects. We believe that the analysis of these RDIS variables, in combination, represents the best available method to address this research question with the smallest degree of error, given the limitations of the available data.

[10]A detailed accounting of the full portfolio of medical research conducted by VA researchers is beyond the purview of this study. VA provides highlights of many innovative and noteworthy research projects at ORD's website at https://www.research.va.gov/research_in_action/default.cfm.

2.3 Qualitative Data Collection and Analysis

The following research questions required qualitative data collection:

1. What is the purpose of the VA NPCs?
   a. Please provide summaries from the statute and VHA Handbooks to clearly define how NPCs are to be utilized.
   b. Are the VA NPCs being utilized to their fullest potential?
2. Who makes the decision as to where a grant will be administered?
   a. What is the local VA policy for the administration of a federal grant involving one of its employees?

5b. Is the NPC a subcontractor on work done at the VA?

7. Is there a policy directing VA investigators with dual university appointments which institution should serve as the grant institution?
8. What is the academic affiliate's policy for the administration of a federal grant involving one of its employees when the research is being performed at the VA?
   a. Do the academic affiliates comply with all VA regulations and policies?
   b. Are they held to the same standards as the VA NPCs?
   c. Do these two policies conflict with one another?
   d. Does it cause a conflict for the employee?
   e. Who manages or resolves this conflict?
9. How does VA benefit when federal grants are administered by the local academic affiliate?
   a. How does the academic affiliate use the indirect fee to benefit VA?
10. What support does the NPC and the university provide to the investigators who submit grants to NIH or other Federal agencies?
11. Does the nonprofit corporation have an explicit education mission in its bylaws? YES or NO
12. Does the nonprofit corporation have the Associate Chief of Staff for Education as a statutory board member? YES or NO

2.3.1 Case Studies

Westat conducted qualitative data collection in two phases. The first phase involved case studies of eight NPC-VAMC-affiliate ecosystems. Early in the study, Westat gathered preliminary data to understand the roles, available choices, and decision-making rationale of various actors involved in extramural grant seeking, preparation, and administration.

Sampling

In conjunction with VA ORD, we selected the following eight VAMC-NPC-affiliate ecosystems: Boston, Cleveland, Cincinnati, Hines, Houston, Portland, Pittsburgh, and San Diego. The study team chose these sites because their NPCs and affiliates manage large amounts of extramural grant revenue on behalf of dual appointed VA PIs, and they represent a range of strategies for determining where grants will be submitted and managed, and for mitigating any potential conflict between NPCs and academic affiliates regarding grant management. Some of these sites were known to have reached agreement about how they will manage extramural grants, while others have not yet reached arrangements satisfactory to all parties.

At each site, we selected for interviews NPC Executive Directors, ACOS-Rs, a representative from the academic affiliate's Office of Research, and two dual appointed VA PIs who have had extramural grants administered by the affiliate, the NPC, or both. ACOSs assisted us with selecting appropriate dual appointed PIs and the individual at the academic affiliate who would be most familiar with the administration of dual appointed VA PIs' extramural research.

In-Depth Interview Protocol Design

Protocols for individuals varied slightly based on the role of the interviewee. We designed separate in-depth interview protocols for NPC Executive Directors, ACOS-Rs, Deans of Research, and PIs. Protocols were tested during the first three site visits and then revised based on interviewer feedback.

Data Collection

Westat conducted four case studies on site: Cincinnati, Cleveland, Houston, and San Diego. The remaining four case studies were conducted over the phone.

2.3.2 Institutional Review Board (IRB) Clearance

Data collection protocols for the case studies, as well as the in-depth interviews at all NPCs/VAMCs, were reviewed and approved by Westat's IRB. Westat received IRB exemption on January 24, 2018.

2.3.3 In-Depth Interviews

The second phase of qualitative data collection involved in-depth telephone interviews with EDs at NPCs, and the ACOS for Research at VAMCs at which there was a collocated NPC. To conduct interviews with the EDs and ACOSs at the locations that were not part of the case studies, we made some revisions to the in-depth interview protocols used during the case studies, incorporating researcher input. Please see Appendix A for the following protocols: "Veterans Affairs Extramural Funding Project Non-Profit Corporation (NPC) Executive Director (ED) Site Visit Interview Guide," and "Veterans Affairs Extramural Funding Project Veterans Health Administration (VHA) Associate Chief of Staff (ACOS) of Research and Development Site Visit Interview Guide."

Sampling

Westat sought to interview the Executive Director of each of the 83 NPCs and the ACOS for Research of each VAMC with a collocated NPC. We did not re-interview the ACOSs and the EDs of Boston, Cincinnati, Cleveland, Hines, Houston, Pittsburgh, Portland, and San Diego, since data had already been collected from these locations during the case studies.

Data Collection

Westat attempted to contact all 83 EDs and ACOSs by phone and by email and schedule a 30 minute telephone interview. The vast majority of EDs and ACOSs were able to be reached and interviewed, but a small number of potential interviewees were not able to be contacted or could not accommodate the interview request. When necessary, Westat made at least three attempts, and up to six attempts, to contact each interviewee. Please see Table 2-1 for a breakdown of final interview counts.

Table 2-1. Interview completion by interviewee type

Interviewee type	Interviews completed	No response	Not available	Post empty	Refused
EDs	72	7	0	2	2
ACOS-Rs	74*	5	2	1	0
Total	**146**	**12**	**2**	**3**	**2**

* One interviewee was ACOS-R at the VAMC and also serving as acting ED of the NPC, and is counted as both an ED and an ACOS.

Data Analysis

With interviewee permission, Westat recorded and transcribed interviews. Interview transcriptions were imported into NVivo, a computer assisted qualitative data analysis software program. Analysts coded all the transcripts manually within NVivo. First, we parsed all data into codes according to the research question the text addressed. Codes included:

- Compare grant submission support from academic affiliate and NPC (Q10),
- Does affiliate subcontract to NPC for work at VA? (Q5b),
- Grant administration policies and practices (Q2, Q2a, and Q7),
- How affiliate benefits VA (including indirect fees) (Q9 and Q9a),
- Now NPC benefits and supports VA (Q10),
- Is NPC used to fullest potential? (Q1b),
- Affiliate compliance with VA regulations and policies (Q8a),
- Academic affiliate and VA/NPC research standards (Q8b), and
- Conflict among academic affiliate and VA/NPC policies (Q8c, Q8d, and Q8e).

The second pass at coding elicited themes among interviewee answers within a single question asked. That is, most interviewee answers could be lumped with others that were similar. For example, most EDs and ACOSs described how the NPCs benefit and support the VA in a range of ways that were similar. Westat identified nine themes that recurred in these interviews including: purchasing computers, laboratory equipment, and supplies; providing opportunities for Veterans to participate in clinical trials; better customer service than many large academic affiliates; pre- and post-award grant administration services, etc. At this point, we were able to assess how robust each theme was, and report on our findings from the interviews on each theme.

Our analytic process was iterative. A single analyst conducted the initial distillation and review of the data in response to each study question to ensure consistent implementation of the study's goals and to ensure uniform comparison of results across the 146 interviews. In order to minimize bias, at least two other study members reviewed initial findings. The group met at each step of the analysis process to discuss and review findings, agree on key themes, and address any gaps and resolve inconsistencies. Often, sub-categories emerged in the course of the analysis within each question.

Summarizing the findings involved discussing the key concepts that emerged from the analysis of each question central to the research project among team members. Multiple drafts were reviewed by the team to ensure quotes were used appropriately, and that key themes and findings were represented accurately. Having multiple reviewers of the data analysis and report ensured the analytic process was systematic and verifiable and that the report was an accurate representation of the analytic findings.

Robust themes tend to occur multiple times across interviews. In these cases, we may qualify a theme (or set of responses) with a modifier such as "some," "many," or "most." When a theme is important to the analysis, but interviewees mentioned it less frequently, we qualify it with modifiers such as "a couple" or "few." For example, when discussing indirect fees, most interviewees did not elaborate on their statement that the VA does not benefit from NIH indirect fees administered at the affiliate. However, the comments of the few who did elaborate suggest why the VA may not benefit. Therefore, we present their perspectives with the qualifier that "a few" gave similar responses. This allows the reader to weigh the strength of the evidence (based on content and frequency) for herself. All opinions described in this report are the opinions of the interviewees.

3. Findings

Q1. What is the purpose of the VA NPCs?

Q1a. Please provide summaries from the statute and VHA Handbooks to clearly define how NPCs are to be utilized.

Congress passed legislation in 1988 (Public Law 100-322, now codified in title 38, sections 7361-66) authorizing the Secretary of the Department of Veterans Affairs to establish VA-affiliated NPCs near VAMCs. The function of these private, state-chartered nonprofit entities is to provide flexible funding mechanisms for the administration of funds, other than those appropriated to VA, for the conduct of VA-approved research. Congress expanded the authority of NPCs in 1999 to include support for VA education and training activities. While most NPCs are affiliated with only one VAMC, the statue allows an NPC to establish affiliations with multiple VA medical centers. NPCs must be established and maintained in accordance with the nonprofit corporation laws of the state in which the NPC's affiliated VAMC is located.[11]

The purpose of the NPCs is to facilitate VA research and education that will enhance the quality of care provided to Veterans.[12] As of 2016, there were 83 independent 501(c)(3) NPCs located in 44 states, Puerto Rico, and the District of Columbia. According to the 2016 Annual Report of the NPCs, from 2006-2015, the NPCs contributed $2.2 billion to VA research and education, and reported revenues of $266 million for the 2016 reporting year, the most recent year for which data were available.

NPCs make it possible for VA researchers to take advantage of funding opportunities from extramural sources, which increases the VA's overall research capacity by capitalizing on research dollars outside its own appropriations. These sources include other federal agencies such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (DHHS), the Department of Defense

[11]Title 38, U.S. Code, sections 7361-7366. Accessed June 18, 2018 from: https://www.research.va.gov/programs/nppo/docs/NPCAuth%20Statute38.doc.

[12](2017) VHA Handbook 1200.17; VA Nonprofit Research and Education Corporations 2016 Annual Report.

(DOD), the National Science Foundation and others. Extramural funding sources also include private industry such as pharmaceutical firms, and other non-profit entities such as foundations whose missions include enhancing Veterans' well-being.

Per the authorizing statue, NPCs must maintain a board of directors that includes:

- The Director of the VA medical center with which the NPC is affiliated (or Directors, in the case of an NPC supporting multiple centers).
- The Chief of Staff of the medical center.
- The Associate Chief of Staff (ACOS) for Research if the NPC has a research mission, and the ACOS for Education if the NPC has an education mission; or, if these positions do not exist, then the individuals who carry out the responsibilities of these positions at the medical center.
- Not less than two members who are not officers or employees of the Federal government and who have backgrounds, or business, legal, financial, medical or scientific expertise of benefit to the operations of the corporation.

One of the responsibilities of the NPC board is to appoint an ED, in concurrence with the VA's Under Secretary for Health. The ED is responsible for the operations of the NPC and may have other responsibilities prescribed by the board. The statue also requires VA to provide ongoing oversight of the NPCs, which is accomplished through three mechanisms. These are: (1) the Nonprofit Program Oversight Board, a senior management body that reviews NPC operations for consistency with VA policy; (2) the Nonprofit Program Office (NPPO), which serves as a liaison between the Department and the NPCs and to which each NPC submits an annual report of its operations; and (3) the Chief Financial Officer (CFO) of the Veterans Health Administration (VHA).

NPCs, like the VA medical centers with which they are affiliated, frequently collaborate with academic affiliates in the conduct of research. VA affiliations with academic medical schools span more than 80 years of history, beginning in earnest after World War II when VA resources and facilities devoted to research were limited.[13] Based on the nature of the relationship between the VAMCs and their academic affiliates, investigators—the majority of whom have dual appointments

[13]Hays, M.T. (2010). *A historical look at the establishment of the Department of Veterans Affairs Research Program.* Accessed June 18, 2018 from: https://www.research.va.gov/pubs/docs/ORD-85yrHistory.pdf

with VA and an affiliate institution—may apply for grants from extramural sources and conduct the research at the VA, the affiliate, or at both locations depending on the nature of the work. Later sections of this report describe and document the factors that influence which institution—the NPC or the academic affiliate—is responsible for the management of grant funds, and how these factors vary among the 83 NPCs. The section below provides summary data on the NPCs as a whole, to include trends in NPC total revenue in recent years, and the number of grants and associated funding amounts managed at the prime level by NPCs and academic affiliates. This information provides important background and context for the presentation of findings on the research questions discussed in the remainder of the report.

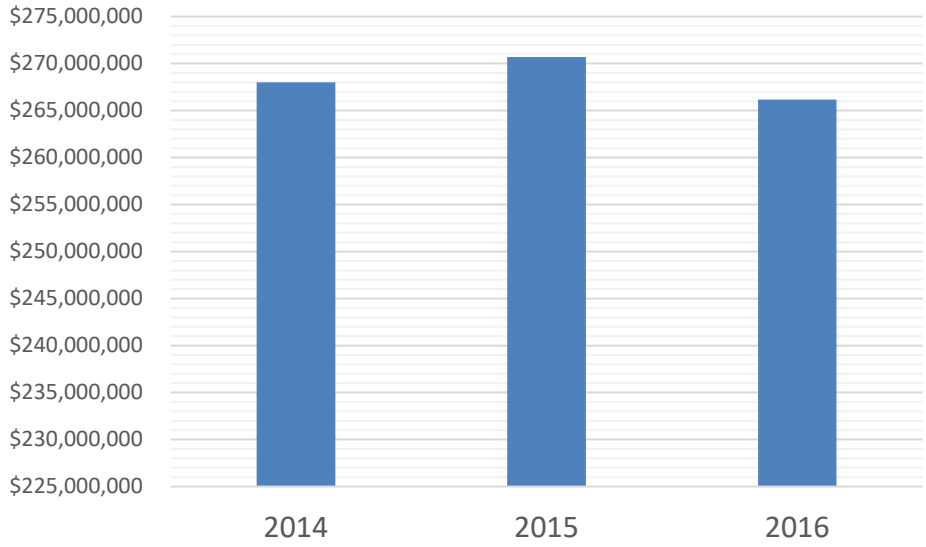
Funding Sources and Annual Revenue of the NPCs[14]

Funding sources for NPCs include government funds, funds from non-government organizations such as private industry and foundations, and a small share of funding –typically around one percent of total funding –from interest income. The large majority of government funding originates in agencies outside of VA that fund medical research through grants, such as the NIH, CDC, DOD and others. Some VA funds come to the NPCs through Intergovernmental Personnel Act (IPA) assignment agreement reimbursements.

The collective annual revenue of NPCs, shown below in Figure 3-1, tends to fluctuate each year as funding agencies' budgets change, the number of NPCs in operation grows or shrinks, and the number of dual appointed VA scientists engaged in research (as well as their success rate in securing grant funding) fluctuates. As shown in the figure, NPCs recorded approximately $268 million in 2014, $271 million in 2015, and $266 million in 2016. Although there were 83 NPCs as of 2016, the ten largest NPCs (as measured by revenue) accounted for more than 61 percent of all NPC revenue in 2016. About half of NPCs—the largest 42—accounted for roughly 93 percent of all NPC revenue in 2016.

[14]The sources for the information provided in this section are the Annual Reports on the operations of Non Profit Corporations submitted by VA to Congress. These Annual Reports document the performance and operations of the NPCs over the prior reporting year.

Figure 3-1. NPC annual revenue 2014-2016



Source: NPC Annual Reports for 2014, 2015 and 2016.

NPC revenue from managing research grants, clinical trials and other projects secured by VA principal investigators includes funds that are awarded to the NPC as a prime, as well as funds that are managed through a subcontract or sub-award received from another organization, typically an academic affiliate. Because several of the research questions in this study focus on which organization tends to administer federal grant funding at the prime level, we briefly summarize below the distribution of funding between NPCs and the VAMC's academic affiliates.

Funds Administered by NPCs and Academic Affiliates in Support of VA Investigators

Table 3-1 displays the number of extramural grants performed by VA PIs in 2014, 2015 and 2016.[15] For each year, the table also shows where these grants were administered (i.e., by an NPC, an academic affiliate, or other entity). The grants in Table 3-1 can be from any extramural source, such

[15]Our source for the quantitative data on the number, size, type, administrator and funders of grants in this report is the Research and Development Information System (RDIS). RDIS is the Veterans Affairs Central Office budgetary and project data repository for managing the VA Research and Development Program. It contains data collected from Veterans Affairs Medical Centers (VAMCs) on all VA research projects. Individual PIs input data on each project they hold into the RDIS on a yearly basis. A single research project can span multiple years, can be funded by a single grant spanning multiple years or through multiple grants from separate funders, and can involve a single or multiple PIs. To simplify the presentation of findings, we focus our analysis on grants entered by investigators for three distinct calendar years: 2014, 2015 and 2016—the most recent years for which data were available. A small share of VA extramural research is conducted at VAMCs without a relationship with an NPC. We exclude these projects from our analysis.

as a federal agency outside VA (e.g., NIH, DOD), private industry, non-profit foundations, or state or local government. To avoid double counting, the table displays only grants and projects administered at the prime level.

Table 3-1. Prime extramural grants conducted at VAMCs with an affiliated NPC, by year

Administrative entity	Number of VA extramural investigator grants by year, all funding sources*		
	2014	2015	2016
NPC	2,493 (58%)	2,511 (60%)	2,414 (59%)
Academic Affiliate	1,503 (35%)	1,385 (33%)	1,340 (33%)
Other	330 (8%)	300 (7%)	327 (8%)
Total	**4,326 (100%)**	**4,196 (100%)**	**4,081 (100%)**

*Prime, extramural awards only. A grant may be performed during multiple years. Only grants with active expenditures in a given year are counted. Column percentages may not sum to exactly 100 due to rounding.

As shown in Table 3-1, VA PIs reported expenditures on more than 4000 projects each year between 2014 and 2016. The average annual number of projects during this period was 4201. On average, the NPCs administered 59 percent of these grants in a given year, compared with 34 percent administered by the affiliates. A small share of investigator projects in each year were administered by another entity, usually the VA itself.

For the same years, Table 3-2 displays the cumulative funding expended from prime awards for all grants managed by NPCs and the academic affiliates. Funding from grants not managed by an NPC or an affiliate are excluded from the table, as are any expenditures from sub-awards. Both NPCs and affiliates manage considerable revenue through sub-awards, but the focus of this section is on prime awards.

Table 3-2. Extramural funding expended from prime awards by VA PIs, by year

Administrative entity	Extramural funding expended by investigators, by year, all funding sources*		
	2014	2015	2016
NPC	$169,216,988 (36%)	$164,010,126 (38%)	$162,205,637 (39%)
Academic Affiliate	$301,807,242 (64%)	$271,253,869 (62%)	$258,349,632 (61%)
Total	**$471,024,230 (100%)**	**$435,263,995 (100%)**	**$420,555,269 (100%)**

*Only prime awards are considered. Table includes funds from all extramural sources—federal, industry, foundations, etc.

As shown in Table 3-2, total annual funding expended by VA investigators at locations with an NPC ranged from $471 million in 2014 to $420.5 million in 2016. In each of the three years, the majority of this funding was managed at the prime level by academic affiliates, but the share of revenue managed at the prime level by the NPCs increased over this period from 36 percent in 2014 to

39 percent in 2016. This increase in the percentage of funding managed by NPCs likely reflects an overall decline in NIH funding in the same the period. As we will discuss in Research Question 3, academic affiliates are more likely to manage NIH funded grants than are NPCs.

The data in Table 3-2, combined with the annual NPC revenue shown earlier in Figure 3-1, indicate that a majority of NPC revenue in each year is managed through prime awards as opposed to sub-awards from affiliates or other organizations. In each of the three years, the share of NPC total revenue accounted for by prime awards was roughly 61 percent or more.[16] During our interviews with NPC EDs and ACOSs for Research, however, we heard that a number of factors influence whether an NPC is likely to administer prime federal grant awards, particular those from NIH. We discuss these factors in our analysis of data collected for Research Question 2.

The combined information from Tables 3-1 and 3-2 illustrates that, while the NPCs manage a larger number of projects as the prime, the average size of projects administered by the academic affiliates is considerably larger. The magnitude of this difference in average project size (i.e., annual funding expended divided by total projects) is displayed Table 3-3. Part of the explanation of the larger average project size administered by affiliates is that large NIH grants tend to be administered by affiliates rather than NPCs. We address this topic in more detail in the analysis of Question 3.

Table 3-3. Average size of expenditures per prime grant, by year

Administrative entity	Average extramural funding expended*		
	2014	2015	2016
NPC	$67,877	$65,317	$67,194
Academic Affiliate	$200,803	$195,851	$192,798

*Only prime awards are considered, to avoid double counting.

[16]This percentage is calculated by dividing NPC prime revenue by total revenue. For example, NPC prime revenue in 2016 as shown in Table 3-2 was roughly $162.2 million. Total NPC revenue in 2016, as shown in Figure 3-1, was $266.1 million. 162.2/266.1 = .61 or 61%

Q1b. Are the NPCs being utilized to their fullest potential?

EDs and ACOS-Rs were asked whether they thought their respective NPCs were being utilized to their fullest potential by VA PIs. The majority of interviewees responded that their NPCs were currently not used to their fullest potential. About a quarter of interviewees told us their NPCs were being used to their fullest potential and a very small number (3 or 4) were not sure.

Because the dominant view was that NPCs were not being utilized to their full potential, below we first describe the main themes that emerged from our discussion with interviewees who expressed this view. ACOSs and EDs described NPCs as not fulfilling their potential because of:

- A lack of staffing and administrative infrastructure at NPCs relative to affiliates,
- Insufficient NPC visibility and promotion,
- Insufficient incentives and supports for dual appointed VA PIs for running grants through the NPCs, and, in contrast
- Strong incentives for, and pressure on, dual appointed VA PIs to submit grants through their academic affiliate.

At the end of this section, we discuss the answers of those interviewees who thought the NPC was fulfilling its potential.

Lack of Staffing and Administrative Infrastructure at NPCs Relative to Affiliates

Many interviewees believed their NPC's small number of staff and lack of infrastructure for handling the submission and administration of federal grants was a barrier to the NPC fulfilling its potential. These interviewees explained that their NPC faced an uphill battle to grow and manage more grants unless they could hire more research coordinators, administrative staff or other specialists:

> *"…you have a chicken and egg phenomenon with –which, the Executive Director –the compensation for the Executive Director is fairly limited and so she's only working part-time for the – for our corporation. And so, now, part of that is just because we have*

limited business to bring her, but then she cannot go out and generate more business."
–ACOS for Research at VAMC in Group 2 [17]

"One of the things that holds us up here is – It's kind of a catch-22 when you have a small or a medium-sized research program. In terms of industry-sponsored grants, you really need to have an experienced study coordinator… The nonprofit corporation has to build up their cash reserves enough in order to hire a study coordinator. But on the other hand, sponsors, industry sponsors, really will walk away quickly from entertaining you as a site to conduct their research if you don't already have a full-time, experienced study coordinator on staff. So we struggle with that. And one of the things we're trying to get the facility to do is for them to invest, at least initially, in hiring a clinical trials coordinator."
–ACOS for Research at VAMC in Group 3

"[The NPC] could get larger. At the moment, we have a very small staff, which matches the kind of amount of work that we need to do. So it's run economically. We have an Executive Director and a part-time finance person. So we don't have a large overhead."
–ACOS for Research at VAMC in Group 2

"We got a lot of laughs at just the horrible condition. Our facility is old and the buildings are decrepit. There's a lot of things that we could be funding if we had the money to do it. That money is going off to [the academic affiliate] now, apparently."
–Executive Director of NPC in Group 1

A few interviewees recognized the challenge of hiring more staff in anticipation of future grant submissions, when the funds were unavailable for such hiring to take place and where hiring could expose a small NPC to financial risk:

"Well, we could easily be administering more and doing more through the foundation and having the foundation do more for our PIs but it's a little bit of a chicken and the egg kind of question or answer. There's got to be some level of investment that goes from the foundation to these PIs for them to buy into what to use the foundation, but then there's got to be money and finances to be able to pump into the foundation to do that. There's got to be some investment. And so a lot of the – in a medium or on a small site or a medium-level site like we are, the foundation doesn't have a lot of money…And right now, it's very small and underutilized and there's not a lot of mechanisms by which the VA can help support and/or grow the individual foundations."
–ACOS for Research at VAMC in Group 2

"And we have a limited number of [trials] – they're sponsoring our research week. But, to be honest with you, I think we're just doing probably 10 percent of what we can do. Yeah. It's like a chicken-and-egg situation. Why were we understaffed? Because we

[17]Speakers are identified only by their role (ED or ACOS) and the policy group of the VAMC with which they are associated. The three policy groups are described briefly in the Executive Summary and in more detail in the results for Question 2. VAMCs in Group 1 have a formal, written policy guiding grant submissions; VAMCs in Group 2 have informal guidelines; VAMCs in Group 3 currently lack a policy and PIs decide where to submit their grants.

didn't have enough money, I guess."
–ACOS for Research at VAMC in Group 2

Insufficient NPC Visibility and Promotion

Many of the NPC Executive Directors and ACOSs believed there was a lack of visibility of the NPC and what they offer to dual appointed VA researchers. Interviewees suggested that very often, VA PIs might **not be aware of either the existence of the NPC** or the advantages to VA of submitting grants through the NPC:

"I would not be honest if I didn't say that maybe 10 percent of the people in this entire building know that we're here."
–Executive Director of NPC in Group 3

"I still find a lot of physicians that don't even know that we exist or what we do, the extent of what we do, what we can do for them. So it's like an ongoing project for me to be able to reach out to them and explain what we do and how we can help them and how they can help us and how we together help Veterans. So there could definitely be a better job when these physicians are coming in, or …at any point or time that they have a meeting with service chiefs and so forth that the NPC is brought up and explained."
–Executive Director of NPC in Group 3

"I think, when I got here, we were kind of a well-kept secret and I don't think a lot of energy was be given toward bringing in new PIs… So one of our jobs or one of our responsibilities that I see is getting it out there. "Hey, if you think you're interested in research, we're willing to work with you. We're willing to help train you. We're willing to facilitate what you need to do research because we realize you've got this heavy clinical load also."
–Executive Director of NPC in Group 3

"Currently, we're just not real visible…we've always been kind of short-staffed and don't have a lot of resources …And I've been taking initiative on my own to learn and try to put as many opportunities out there for the researchers and try to be visible and have a useful website and that sort of thing, just to do what we can to try to encourage more research and more research on VA property and more VA research. Hopefully, funded and supported through the NPC."
–Executive Director of NPC in Group 3

Even when PIs are aware of the existence of the NPC, interviewees explained PIs are unlikely to know the range of services the NPC provides. Interviewees also said that some PIs perceive the NPC lacks the capability or experience to effectively administer a federal grant, especially in comparison to their university affiliates, whose administrative bandwidth and infrastructure is frequently perceived as superior:

"I do think the affiliate has more experience doing NIH grants. I think it might be better for the PI, in their mind, to go through [the affiliate] just because they have more of a system in place to help support that."
–ACOS for Research at VAMC in Group 3

"They automatically assume, 'well, you guys [the NPC] don't have the infrastructure."
–ACOS for Research at VAMC in Group 2

Some interviewees also noted a lack of effective collaboration and communication among the ACOS, the NPC, and investigators:

"…the interactions between the busier and the less research-experienced investigators and the non-profit have been developing slowly in a bunch of cases. … the head of the R&D committee, is really going out of her way to mentor a number of the junior investigators who are positioned in really key Veteran patient populations... The disconnects are even greater … So there's just a lot better need for coordination between the non-profit, the research office, the university, and the investigators."
–ACOS for Research at VAMC, Group 2

"There's too many of them that don't know about us. Our ACOS for research…I think he has probably too much on his plate. I also think part of it is…it's not in his wheelhouse. It's just not who he is... He figured the [PIs] could come to him…it makes it really hard to increase the research program…"
–Executive Director of NPC in Group 3

Insufficient Incentives and Supports to VA PIs

Interviewees attributed the deficit of clinical researchers to a **lack of incentives for clinical research within the VA system and inadequate supports to prospective researchers**. Some respondents pointed to a lack of financial incentives and others to a lack of career advancement incentives.

"…I believe in the 30 plus years that I've been involved in research for the VA is that we seem to have fewer investigators who are interested in doing research. I think that years ago there was more of a push towards scholarly work, research, publishing, but I think the emphasis has shifted to more clinical work, to seeing more patients, delivery of care, and has shifted away from research. And I think also part of it may be generational because unless you're wanting to do research to satisfy some inner need of funding yourself …there's probably no direct financial benefit of investigators who conduct research. They're paid by the VA to see patients."
–Executive Director of NPC in Group 1

"So I will take you back to 2006, 2007. At the time, the research was a metric of the performance of all physician, core physician, and principal investigator PhDs. And at the

time, the research at the VA was booming. And at some point, these research components have been taken out from the evaluation metrics. So the research went down, and the PI doesn't see any – I'm not saying most of them, but I'm saying a big percentage, maybe 70 percent, saying that, 'If I do research or I don't do research, it's not really a value for my career.'"
–Executive Director of NPC in Group 1

"[NPC] business could be brisker…I'm doing as much research as I can myself. We'd all be doing more if we had time to do more. We're held so much to the RVU [Relative Value Units] standard, and with very little in the way of formal recognition for research efforts, that that's what's limiting our NPC activity."
–ACOS for Research and ED at VAMC in Group 3

A few interviewees pointed out that the VA's central mission continues to be clinical with the research endeavor lagging far behind.

"…one of the problems that our VA faces …is insufficient, to coin a word, 'academization' of its clinical services…on a day to day basis [the VA's mission] is really defined by the exigencies of clinical care, and when clinicians are recruited to specialty services, they are recruited because of their clinical qualifications and people don't often even introduce the idea of research …So to the extent that we can academize our clinical services we can markedly expand the number of studies that the non-profit is sponsoring."
–ACOS for Research at VAMC in Group 3

"The focus of the medical director is clinical time, and research is second. And so the focus is clinical basis. So if any physician wants to go into research, it's almost at their detriment to do that."
–Executive Director of NPC in Group 3

A specific concern of interviewees raised numerous times pertained to the **lack of protected research time** for VA PIs. It was suggested that VA clinicians have no time to submit grant applications and conduct research.

"…we could probably be doing a huge amount of work, as far as clinical research goes. I think, there's some pushback from the hospital side. So it's not really from the university, this is from our own hospital. And a lot of that comes down to … provider time. When you have a backlog of patients that need to be seen, and you have a deficit in square footage to treat those patients, research does not become a priority."
–Executive Director of NPC in Group 1

"We don't have a lot of mentoring capabilities…The PIs will say they don't get protected time to do research."
–Executive Director of NPC in Group 3

> *"It just seems that there are a lot more clinical responsibilities, and there are less clinical investigators around. Even at the university … all of the stresses and strains of seeing patients these days, which is not just seeing the patient, but all of the other regulatory stuff and new paperless medical record systems that require a lot of time. It's been hard to find clinicians willing to do clinical research. That's why with my job as ACOS I feel their pain, and what my job is to try to help them… I thought my time would be best utilized helping them get these things started, because they just – they don't have time to do all of the paperwork."*
> –ACOS for Research at VAMC in Group 3

At some of the smaller sites, interviewees claimed that their VAMCs are currently experiencing **a deficit of physicians interested in clinical research**, leading to a decreased demand for NPC services.

> *"Do we have enough experienced PIs that are getting sponsored trials? So I think that's the issue…So I think for the PIs that have sponsored trials, I think they get good service from the NPC. But I think what I'd like to do …is get more of the younger investigators involved."*
> –ACOS for Research at VAMC in Group 3

> *"We just don't have that many investigators wandering around in this building. I mean, we're gutted. There's so many that have left…But are investigators doing what they can do, the investigators that we have? Yes."*
> –ACOS for Research at VAMC in Group 3

One NPC Executive Director characteristically said:

> *"… our VA medical center's research portfolio [is] a sleeping giant…There's a lot of PIs, a lot of great talent and interest. But it's very slow to get the PIs and their bosses in the administration within the VA medical system to embrace it."*
> –Executive Director of NPC in Group 1

Affiliates Incentivize and Pressure PIs

When EDs and ACOSs discussed policies and decision-making regarding where grants should be administered, many noted that dual appointed VA PIs feel considerable career pressure to submit their NIH grants—or sometimes all federal grants—through the academic affiliate. Several interviewees characterized this dynamic as a conflict of interest, since it may encourage decisions based on factors other than what is best for the VA or for Veterans. Others considered this dynamic a normal part of an academic career, in which faculty support the university's goals by bringing grants to the university, and receive salary support for work performed above a 40-hour workweek, tenure, and promotion:

"And one of the interesting aspects, if you have a salary position at the university, you arguably have an institutional conflict of interest, just with that where you'd be pressured to have as much of those resources, either intramural funds or extramural funds, flow to the benefits of the students and the other people at the university side. So that's an interesting issue in the background all the time. And we basically have to look at how the PI – especially our research career scientists, are walking that tightrope, keeping the university happy with the extramural funding that they bring in, and keeping us happy with ORD intramural funding that they maintain.
–ACOS for Research at VAMC in Group 3

Some dual appointed PIs receive an 8/8ths salary at the VA, and work additional hours at the affiliate to run their extramural grant research. The additional hours generally do not exceed 20, and those 20 hours of salary must be covered by the PI's extramural grant. Several interviewees explained that the VA is limited to paying salary based on a 40-hour workweek and that NIH regulations prohibit the use of grants funds for compensating dual appointed PIs beyond 40 hours **if the NPC manages the grant**. These interviewees told us that, if the PI were to submit their NIH grant through the NPC, he or she would not be able to cover their academic salary through that grant, effectively limiting their compensation to their 40-hour workweek at the VA. Some interviewees perceived this as incentivizing PIs to run their NIH grants through the affiliate:

"The affiliate can pay a full-time federal employee from an NIH grant because they have an MOU with NIH that says 'we recognize that VA employees…with a university appointment…their typical workweek would be 60 hours'….Therefore, the NIH allows the university to pay faculty a salary from an NIH grant in addition to their full-time VA salary. The NPC cannot do that."
–Executive Director of NPC in Group 1

"They [PIs] don't consider it a benefit to go through the NPC…The academic affiliate gets them extra salary dollars if they will go through them."
–Executive Director of NPC in Group 3

"There are things that the affiliate can do that the VA nonprofit cannot…A clinician-scientist who wants to be paid above their VA tour, that's a real wrinkle because of federal rules…There are many people who work more than 100 percent. And that's important because that advances both the academic enterprise and the VA's efforts in parallel."
–ACOS for Research at VAMC in Group 1

Other dual appointed VA researchers may split a 40-hour workweek between VA and the affiliate. In this case, a dual appointed VA PI may receive 5/8ths of their salary through work at the VA, and be expected to make up the remaining 3/8ths of their salary with professional activity (i.e., time-limited grants and contracts) at the academic affiliate. As cited below, an ED explained that dual

appointed VA PIs, depending on how they split their time between VA and the affiliate, must find funding to support their academic affiliate salary:

> *"The majority of them [dual appointed VA PIs] are going through the affiliate university because of salary coverage. Investigators have university salary that must be covered through research, whereas any research on the VA side is covered by the VA. So their need to ensure that their salary is covered on the university side dictates that the study needs to go through the university, and that generally means that the bulk of the budget is going to be on the university side because of their salary costs."*
> –Executive Director of NPC in Group 3

> *"…there's a lot of pressure, especially on the PIs…[and] the department as well, to be able to support themselves with research funding. And if they can't do that, then what typically happens is either their salary is reduced to some extent or they're forced – if they're clinicians – to move into more clinical activities…thus less time for doing research."*
> –ACOS for Research at VAMC in Group 3

> *"So PIs are obligated to the university to account for their effort and if a PI, for example, needs efforts to be covered on the university's side, frequently they will have the university administer the grant."*
> –ACOS for Research at VAMC in Group 3

Besides salary, interviewees mentioned other career-oriented factors that serve as incentives for dual appointed PIs to choose the university over the NPC when considering through which organization to submit their grants, including the expectations of their department chairs and the fact that successful grants can enhance the investigator's chance for promotion or tenure:

> *"[Prior to current policy] PIs brought their grants through their university because there's an incentive for them to do so. It helps with their department head's perception of their work and their contributions. It helps them towards their promotability, and publishing of papers…giving credit to the university."*
> –Executive Director of NPC in Group 1

> *"I think [PIs] prefer [their grants] to go through the academic affiliate because of the academic credit they get for it, as I mentioned earlier. So what we're trying to do is make a case that it's actually easier and more efficient to submit it through our NPC."*
> –ACOS for Research at VAMC in Group 3

Many interviewees used the term 'pressure' to describe the circumstances faced by dual appointed PIs considering where to submit their grants, and/or by the department heads for whom they work.

> *"In my perspective it has not been the PIs; it's been the university administration…They are under tremendous pressure to bring every federal dollar they possibly can through the*

university."
–Executive Director of NPC in Group 1

"[The affiliate] puts an awful lot of pressure on them [PIs], even to the point of telling them, 'if you don't run that study through this department, you can lose your appointment.'"
–Executive Director of NPC in Group 3

"I mean, I think for a lot of things, we're still an afterthought. It's very hard to change the mentality…what's been done for so many years, and it's hard to change it when we know that they're getting pressured from the university."
–Executive Director of NPC in Group 1

Some interviewees explained that university administrators experience ongoing competition for finite research dollars to support the university as well as pressure to support the affiliate's national ranking. They explained that NIH grants are the currency through which prestige is measured and reflected in national rankings, and that pressure flows down to PIs:

"The NIH grants are part of the currency for the [affiliate's] academic reputation…that's a critically important component of how competitive they are among peer institutions nationally"
–ACOS for Research at VAMC in Group 2

"I think that also there is the perception that there's greater value added if they utilize the university rather than utilize the nonprofits. I think that there are a lot of people here who view their appointment, whether it's an actual appointment or just an on-paper appointment with the university, to be much more prestigious for their curriculum vitaes and so forth, than saying that they're – rather than being affiliated with the NPC. I think that there are many people here who are full-time employees, and the first thing that – I mean they don't even use VA email. They use the university's email."
–Executive Director of NPC in Group 1

Interviewees Who Believed the NPCs Were Fulfilling their Potential

About a quarter of respondents felt that their NPC was fulfilling its potential and in some cases even growing:

"Yes [we are fulfilling our potential]. We're very lean, and we've made an effort to be efficient in terms of staffing. I mean, essentially the VA NPC is run by the Executive Director and an accountant, period. And we've done that to ensure that we don't incur any deficits in our administrative core, in the foundation, and we've actually been profitable over the past year or two for that reason."
–ACOS for Research at VAMC in Group 3

"So, we are in a rebuild mode for our foundation so I would say yes [we are fulfilling our potential]. I hope that the foundation – it went through a tough period. We were kind of at a low and now we're kind of building it up again so I think right now, yes. I hope that the foundation is going to grow. It's on a nice upward trajectory for the past, basically, seven months and I'm hoping that we'll be able to offer even more and it will be able to offer more as it continues to grow and solidify."
–ACOS for Research at VAMC in Group 1

Interviewees who felt their NPCs were fulfilling their potential frequently gave one of two qualifications. Many felt their NPC could simply not handle more grant submissions even if they wanted to, due to their limited staff and resources:

"I think that they are [fulfilling potential], given its capability. Our NPC is currently growing, and as it grows, it is offering more services. I believe they are serving the PIs to its fullest capacity, but it's rather a small NPC."
–ACOS for Research at VAMC in Group 3

"…our shop is not very large. So we only have two people that actually run the nonprofit. We basically have the Executive Director, who you'll be speaking to, and then she has basically an assistant. …So, given the size and the number of PIs here who have active grants now – it's about a dozen or so…There's not much more ours can handle with its current staffing. But we also don't bring in enough to expand it either, so we're kind of stuck where we are".
–ACOS for Research at VAMC in Group 2

"It's very busy…it would have to increase its size and then it'd have to maintain the research and so it becomes kind of a waste, which really isn't serving the Veterans. So, right now, I think it's actually perfectly sized to the meet the needs of the facility."
–ACOS for Research at VAMC in Group 2

A few interviewees felt that there was just not enough interest in research and/or PIs in their respective VAMCs for them to be able to ramp up their operations. The latter was a common theme also among interviewees who felt their NPCs had more room to grow, as described above.

Summary for Question 1b

- The majority of EDs and ACOSs stated that their NPCs were not being used to their fullest potential.
- Below are the main reasons ACOSs and EDs provided for why the NPCs have as-yet untapped potential:
  - Relative to affiliates, NPCs lack staffing and administrative infrastructure;
  - NPCs are insufficiently promoted and not visible;
  - Dual appointed VA PIs are insufficiently supported and not incentivized to run their grants through the NPCs;
  - Dual appointed VA PIs experience strong incentives for, and pressure to, submit grants through their academic affiliate.
- About one fourth of EDs and ACOSs said the NPCs were being used to their fullest potential

Q2. Who makes the decision as to where a grant will be administered?

Q2a. What is the local VA policy for the administration of a federal grant involving one of its employees?

Q7. Is there a policy directing VA investigators with dual appointments which institution should serve as the grant institution?

In this section, we address research questions that focus on policies and procedures in place at VAMCs that govern or influence decisions about where VA investigator grants are administered.[18] Research Questions 2, 2(a) and 7 focus on the topic of how decisions are made regarding where grants led by VA-employed investigators will be managed, and what policies, if any, influence or determine this decision. Because these are related questions, we address them together in this section. We begin by defining the phrase "policy for the administration of a federal grant" for the purposes of this report. We then summarize the major themes that emerged from our interviews with NPC Executive Directors and Associate Chiefs of Staff for Research at the 78 locations from which we gathered data.

Definition of "Policy for the Administration of a Federal Grant"

For the purposes of this report, we define a policy regarding grant administration as formal set of instructions or guidance, codified in writing (e.g., in a memorandum or list of standard procedures), established by the leadership of the VAMC and communicated to the employees and staff whose work the policy affects. A grant administration policy, for our purposes, clarifies in an unambiguous way what criteria are to be considered in the decision about where a grant will be submitted and administered, the circumstances in which exceptions can be made, and who decides if an exception is warranted. Policies may include a direct agreement (such as a Memorandum of Understanding) between the VAMC and their academic affiliate.

Key to our definition is that a grant administration policy is documented in writing and communicated to staff. Absent these characteristics, a VAMC may still have informal procedures or guidance, or generally accepted ways of doing business that influence decisions about grant

[18]The term "local VA" as it appears in Question 2(a) has been replaced throughout the report with the term VA Medical Center, or VAMC.

submission and administration. Informal guidance or rule of thumb processes based on what has been done in the past do not, however, constitute a policy for our purposes. Although we recognize there are many ways to define policy, we employ this definition because it allows us to differentiate VAMCs at which formal written procedures, which are more easily enforceable, are present, versus VAMCs where less formal methods are used.

It is important to note that the existence of a formal written policy does not necessarily mean the policy is always followed in practice, nor do we suggest that informal guidelines are never effective. Later in this section, we present interviewees' insights on differences in policy and practice, and their views on how well existing rules or guidelines in place at their locations are working.

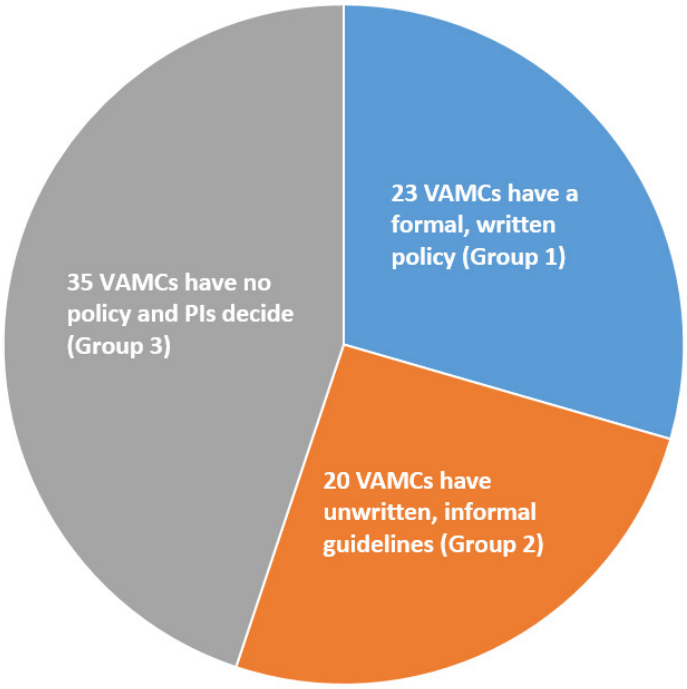
There is no single policy across VAMCs that addresses the issue of where VA investigator grants should be managed and under what conditions. Collectively, interviewees described a range of approaches regarding how grant administration decisions are made at their local VAMC/NPC.

Interviewees described a wide range of scenarios with respect to the policies and procedures in place at their VAMC/NPC to address submission and administration of extramural grants conducted by dual appointed VA investigators. Based on more than 140 interviews with NPC Executive Directors (EDs) and Associate Chiefs of Staff for Research (ACOSs), we found that VAMCs tended to fall into one of three general groups when we asked about this topic. These groups were:

1. VAMCs with a formal, written policy on extramural grant submission and management.
2. VAMCs that have a set of preferred guidelines or informal procedures, but no written policy.
3. VAMCs where Principal Investigators (PIs) decide where to submit their grants and there is no written policy or informal guidelines.

Figure 3-2 shows the relative size of each of these three groups. At 23 of the 78 sites with which we conducted interviews, interviewees told us the VAMC had a formal, written policy determining where grants should be managed. At 20 sites, interviewees explained they followed an unwritten, informal set of guidelines or procedures. The largest group (35 sites) comprised VAMCs where interviewees told us they did not have a policy, and that PIs decided which organization—the NPC or the academic affiliate—would submit and manage their extramural grant.

Figure 3-2. Number of VAMCs with or without policies governing extramural grant administration



It is important to stress that we base these groups on interviewees' responses to questions about their local policies for determining grant administration, not their views about what happens in practice. We heard many examples of differences between policy and practice, such as VAMCs where written policies or informal guidelines exist but where PIs make the decision in practice. We also heard of examples in which no written policy exists but where local informal guidelines and procedures are followed nearly all the time. We discuss these themes later in this chapter. Below, we describe the common characteristics within each of the three groups of VAMCs/NPCs shown in Figure 3-2.

Group 1: VAMCs with formal policies guiding decisions about where grants should be managed

There are 23 VAMCs/NPCs where interviewees said there was a formal, written policy in place to that specifies where an extramural grant should be submitted and managed under given conditions. Many VAMCs in this group have policies that share similar or identical features. Specifically, many

of the formal policies state that VA investigators' extramural grants should be administered at the NPC if the preponderance of work (51% or more) will be conducted at VA:

> *"There is a mutual agreement between our affiliate and the nonprofit as to where the research grant will be administered. When a PI contacts us, we look at the budget items to help us decide whether work is being conducted and if the predominance of the work—more than 50 percent—takes place at the VA, then the administrating entity is the NPC."*
> –Executive Director of NPC in Group 1

> *"We have a memorandum of understanding, an MOU, between our organization [the NPC] and our academic affiliate…it identifies that the grants will be administered by either [the affiliate] or [the NPC] depending on where the preponderance of work takes place. That's what is stated in the MOU."*
> –Executive Director of NPC in Group 1

Preponderance Rule. The large majority of VAMCs with a formal grant administration policy apply the "preponderance rule". This rule directs the prime administration of the grant to the organization at which the majority of work—as defined by planned budget and expenses associated with the research—will take place. Interviewees told us that determining where the preponderance of the work takes place involves consideration of a number of factors, such as where the patient population is coming from (Veterans vs. non-Veteran research subjects), which organization's laboratories or facilities will be used, (VA or NPC labs vs. affiliate labs), and the staffing mix (VA or NPC employees versus affiliate employees). In budget planning, each of these elements can affect the investigator's calculations regarding where the majority of the grant's funding will be expended.

With some exceptions, VAMCs with formal policies based them on where the preponderance of work will be conducted. We refer to this as the "preponderance rule".

In some VAMCs that have established a written policy based on the preponderance rule, the source of the extramural funding (e.g., federal vs. industry or non-profit funds) is not a factor when determining the appropriate agency to administer the project. That is, their policy states that if the investigator's grant or project is going to be performed mostly or fully at VA and/or with VA patients, then the NPC is the appropriate organization to manage the project regardless of funding source:

"The rule is that NIH, DOD, and pharmaceutical trials are to be administered via the non-profit unless more than 50 percent of the performance is at the affiliate."
–ACOS for Research at VAMC in Group 1

Not all VAMC's in Group 1 that use the preponderance rule apply it to all sources of funding, however. At several sites, interviewees explained their VAMC's policy exempts NIH funded grants (or sometimes all federally funded grants) from the preponderance rule. At these sites, the rule applies only to industry trials and other projects funded by non-federal (or non-NIH) sources, with the policy directing that NIH grants (or sometime all federal grants) are to be administered by the affiliate:

"[The academic affiliate] signed off a memorandum of understanding between the local VA administration [such that] that industry grants and pharmaceutical grants can be administered by the nonprofit if the studies are conducted at the VA Medical Center. But our NIH or other federal funding grants need to be administered at the affiliate."
–Executive Director, NPC in Group 1

Other Rules for Determining the Grant Management Entity. Not all VAMCs with written grant administration policies use the preponderance rule to determine the managing entity. Interviewees at a few VAMCs explained that their formal policy is primarily based on the percentage of time the PI is committed to VA. Dual appointed researchers split their time between the VA and the academic affiliate, with the split expressed in "eighths". For example, a PI who is "five-eighths" VA is expected to perform that fraction of a 40-hour workweek on his or her VA duties, with the remainder of their time performed at (and compensated by) the affiliate. VAMCs that have a grant submission policy based around the investigator's VA time commitment typically direct PIs with a certain number of "eighths" to submit their grants through the NPC:

"Any investigators who have at least a three-eighths appointment here at this VA and conduct non-VA funded research, whether it be federally funded by NIH, DOD or industry or philanthropy, et cetera…and the bulk of that research is conducted here at the VA Medical Center, the monies must come through our nonprofit corporation."
–ACOS for Research, VAMC in Group 1

It was our Director's decision here that if you are more than 50 percent VA employee you should be submitting your grant through our foundation to promote our NPC."
–ACOS for Research, VAMC in Group 1

MOUs. Some interviewees said their VAMC's policy took the form of a Memorandum of Understanding (MOU) between the VA and the academic affiliate that both parties have signed, indicating their mutual intent to follow the preponderance rule (or other jointly negotiated policy) to

determine which organization should administer the grant. In other cases, the policy is not countersigned by the university, either because the VAMC has determined an MOU is not necessary, or because the affiliate does not concur with the policy. Even when there is no MOU however, interviewees at most sites in Group 1 told us the policy is communicated to dual-appointed VA researchers by the ACOS or the R&D Committee. Investigators are expected to abide by the policy unless there are extenuating circumstances, which require approval by an individual or committee providing oversight on behalf of the VAMC—such as the R&D Committee or the ACOS.

Interviewees at several of the VAMCs and NPCs in Group 1 told us that their MOUs were working well and helped minimize confusion, and some said their policy reduces the potential for conflicts of interest. Even at locations with a successful MOU, however, interviewees explained that negotiations to establish these agreements can be contentious and that they are challenging to set up. Interviewees said that MOUs require ongoing negotiation and communication between the VAMC and the affiliate, and can take many years to finalize. Some interviewees explained that their MOU had only recently been signed or had not been in place long enough to judge whether it was an effective policy.

The 23 NPCs that are collocated with VAMCs that have a formal, written grant administration policy accounted for 62 percent of revenue reported by all NPCs in 2016

Not all interviewees at sites with a formal policy had an MOU with their academic affiliate. Some VAMCs instead have a written memo from the VAMC Director articulating the policy, or a set of Standard Operating Procedures (SOPs) that has been developed by the R&D Committee and put in writing. VAMCs that do have formal MOUs with their academic affiliates tend to be, but are not always, located on the West Coast, and their associated NPCs tend to have much higher than average annual revenue and a larger number of employees compared to other NPCs.

Summary of VAMCs in Group 1

- Twenty-three of the 78 VAMCs/NPCs with which we conducted interviews said they had a formal, written policy directing extramural grant submission and management.
- The majority of the VAMCs in Group 1 use the "preponderance rule" as the basis of their policy. The preponderance rule directs investigators to submit their grant or project through the NPC if more than 50% of work will be performed at the VAMC or with VA patients.
- A few VAs rely on the percentage of time the investigator is committed to VA, as expressed in eighths, as the basis of their formal policy.
- VAMCs in Group 1 tend to be concentrated on the West Coast, but they are found in other parts of the country also.
- Some VAMCs that have codified the preponderance rule in their policy specifically exempt NIH funds, or sometimes all federal extramural funds, from application of the rule.
- As a group, NPCs associated with VAMCs with formal written policies on extramural grant submission and administration are larger and have higher revenue, on average. The 23 NPCs in this group reported $162.4 million in revenue in 2016, or approximately 62 percent of the revenue reported for all 83 NPCs in 2016.

Group 2: VAMCs with no formal written policy but with informal guidelines

Interviewees at 20 VAMCs and their associated NPCs told us their VAMC has informal guidelines, rather than a formal written policy, that are used to guide investigators as to the appropriate organization to submit and manage a particular grant or project. Informal guidelines represent a traditional way of doing business rather than a set of formal procedures, and we found VAMCs in this category generally, but not uniformly, work with investigators to ensure they are aware of the guidelines. Specific guidelines vary from site to site, but those used most often are similar to the policy criteria in effect at most VAMCs in Group 1, which are based on work share. That is, the most commonly used informal guidelines in place at VAMCs/NPCs in Group 2 stipulate that if the majority of the work is to be performed VA, then the NPC is the appropriate organization to submit and manage the PI's grant:

> *"We don't have a policy locally on that matter. Essentially, we follow a practice that, if the VA employee is going to be doing [the research] on VA time, if it's going to involve Veterans or VA resources will be used, the VA will be engaged in that research and if it's not a VA-funded study, then [that research] will be administered either by award to the NPC or a sub-award."*
> –ACOS for Research, VAMC in Group 2

> *"Well, where the majority of the work is done would be the location where the grant would be administered. That's the logic that has governed our operation from day one.*

And it seems to be working quite well for us."
–Executive Director, NPC in Group 2

Interviewees at VAMCs/NPCs across all three groups told us that the NPC manages most or all of the industry-sponsored projects brought in by VA investigators. They explained that industry clinical trials are typically governed by a Cooperative Research and Development Agreement (CRADA) between the industry sponsor and the VA. Interviewees told us that, because these agreements focus exclusively on Veteran patient populations, are frequently led by VA researchers without university appointments, and might not cover the university's full overhead rate, academic affiliates are typically not involved in their management or execution.

Group 2 interviewees often told us, however, that many or most of the federal grants conducted at the VAMC—particularly the NIH grants—are administered by the academic affiliate rather than the NPC. In some cases, the guidelines that interviewees described contained an exception for NIH-sponsored grants, so that the affiliate usually administers them:

"The unwritten rule for our organization is that any of the NIH prime awards go through [the academic affiliate] if they're [submitted by] dual appointed personnel... and that's regardless of where the work is conducted. Any of the other awards…if they're conducted at least 50 percent time at the VA, then they come to [the NPC]."
–Executive Director, NPC in Group 2

"I do not believe there's anything written…it's an informal agreement that we follow. We have a really good working relationship with our affiliate. It works because we can offer the sub-award…so [the affiliate] receives the prime award [from NIH], and we can administer a sub-award off of that."
–Executive Director, NPC in Group 2

Some interviewees at VAMCs/NPCs in Group 2 told us that they were in the process of moving from a set of informal practices to a formal, written policy that would result in new grants being managed at the NPC, whereas under the old practices they would be administered by the academic affiliate. For example, one interviewee said a recommendation was underway at their VA to formally establish the preponderance rule as policy:

> *"There's a recent medical center memorandum I have seen initiated by the Research and Development Committee here that says if it's 100 percent Veteran participants or greater than 50 percent of the work, that it will be administered at the non-profit…. We're planning to do an SOP. It's in the process of being drafted."*
> –ACOS for Research at VAMC in Group 2

Another interviewee from Group 2 explained their VA was working towards establishing a formal policy based on the percentage of time that the PI is committed to VA:

> *"I am negotiating with [the affiliate] on this, so this isn't policy yet. This is in the early stages of negotiation…If [a PI] is here in the VA, and they have a dual appointment but their labs are in the VA and they spend greater than 80 percent of their time here…their NIH grant should be run our nonprofit…Any new NIH grants that are submitted will be run through our nonprofit."*
> –ACOS for Research at VAMC in Group 2

NPCs associated with VAMCs in Group 2 were of a wide range of sizes, ranging from approximately $40,000 to several million dollars as measured by 2016 revenue. Unlike their counterparts in Group 1, VAMCs/NPCs in Group 2 are not concentrated in any particularly geographical area but spread throughout various the parts of the country.

Summary of VAMCs in Group 2

- Twenty of the 78 VAMCs/NPCs with which we conducted interviews said they did not rely on a formal written policy directing extramural grant submission and management, but instead used informal guidelines or time-honored procedures.
- The most common guideline used to advise PIs on grant submission and administration at VAMCs/NPCs in Group 2 was some form of the preponderance rule: if the work will be performed mostly at VA, then the appropriate organization to submit and manage the project is the NPC.
- Some VAMCs in Group 2 have informal guidelines or traditional practices that specifically direct NIH grants, or sometime all federally funded extramural grants, to the affiliate while directing all work funded by industry or non-profit associations to the NPC.
- Interviewees at a few of the VAMCs/NPCs in this group explained they were in the process of implementing a written policy to replace their informal guidelines and practices.
- NPCs at VAMCs with informal guidelines rather than written policy are of a wide range of sizes and not concentrated in any single part of the country.
- The 20 NPCs in this group reported $57.2 million in revenue in 2016 or approximately 21 percent of all revenue reported by all 83 NPCs in 2016.

Group 3: VAMCs where the PI decides and there is no current policy for grant submission and administration

Interviewees at 35 VAMCs/NPCs explained that principal investigators make the decision about where to submit and have their grants administered and there is no local written policy or set of informal rules used to determine which organization should administer a particular grant:

> *"At the present we don't have a policy that governs that question. So, practically speaking, the PI that has a dual appointment at the affiliate and at the VA, they actually decide which way they're going to go with their grant, whether the nonprofit, the VA's going to administer it, or the affiliate is going to administer the grant… They usually go with the affiliate if it's an NIH grant. If it's industry-sponsored, then they go with the nonprofit corporation."*
> –ACOS for Research, VAMC in Group 3

Interviewees at the majority of the 35 VAMCs/NPCs in Group 3 emphasized that extramural grant submission and administration decisions were made by the PI rather than determined by policies or guidelines:

> *"Since I've been here there is not, per se, a policy that is in place…It is the investigators who actually decide whether or not that particular grant…will be administered through the academic affiliate or with the nonprofit."*
> –Executive Director of NPC in Group 3

> *"Well, [the decision] is usually made by the PI of the grant. We've been trying to encourage [researchers] to participate with NIH and DOD or commercial entities by going through our non-profit."*
> –ACOS for Research, VAMC in Group 3

It is important to note that some interviewees at Group 1 and Group 2 also told us that, at their sites, PIs sometimes end up making the decision despite the existence of policy or guidelines. We discuss differences in policy and practice following this overview of Group 3 locations.

Some interviewees at VAMCs/NPCs in Group 3 told us they did not have a policy because of the particular circumstances at their location. For example, some VAMCs and NPCs do not have an academic affiliate and few or no dual appointed investigators. In these cases, because there is no affiliate, interviewees explained a policy was not necessary; the NPC represents the only choice to handle extramural funds:

> *"We don't really have an academic affiliate here. So that issue doesn't come up for us."*
> –Executive Director, NPC in Group 3

> *"It's less of an issue here because we don't have sort of the robust academic affiliate compared to a lot of other sites…I'm not aware from a policy. Because it's never been a problem, I've never had to research or to develop a policy."*
> –Executive Director, NPC in Group 3

Interviewees at several of the smaller VAMCs and NPCs in Group 3 explained there is little to no history of NPC-managed federal grants, or described a limited capacity to manage the requirements of complex federal grants, which effectively limits their policy options. For example, some interviewees said their NPC was small with few or no full time staff, whereas the affiliate, by comparison, has a large and experienced administrative department whose sole focus is on managing federal grants:

> *"No, there aren't [existing policies or guidelines]. We have talked about this. We discussed it with the board of directors for the nonprofit…If the NPC started bringing in more funding where they could afford to hire another person, then I would say that…we want [the grants] to go through the NPC initially, without the subcontract. But we have to be realistic…right now, the NPC fully couldn't manage everything it takes to manage an NIH or a DOD-funded grant."*
> –ACOS for Research, VAMC in Group 3

> *"We haven't had that [NIH grants] happen since I've been here as far as a new extramurally funded study…We do have industry-sponsored trials… You know, we don't have high-power folks getting RO1 grants… [The affiliate] has dedicated folks that just basically do NIH grants. It's not a large team, but it's certainly more than the NPC has here."*
> –ACOS for Research, VAMC in Group 3

On average, NPCs associated with VAMCs in Group 3 are smaller as measured by annual revenue than those in Groups 1 and 2. About two-thirds of the NPCs in Group 3 had revenue under $1 million in 2016. Like their counterparts in Group 2, VAMCs/NPCs in Group 3 are found throughout all parts of country.

Summary of VAMCs in Group 3

- **Thirty-five of the 78 VAMCs/NPCs with which we conducted interviews said that PIs decide whether to submit extramural grants through the NPC or the affiliate and that their VAMC did not have a grant submission policy.**
- **At some sites, interviewees attributed the absence of a policy to the individual circumstances of their VAMC/NPC. For example, some VAs do not have an academic affiliate, making the NPC the only option for the management of extramural funds.**
- **A few interviewees described their policy options as limited, because they had a small or inactive research program, very few PIs, or the NPC lacked capacity (e.g., staff, experience) to manage the requirements of an NIH grant.**
- **While not all NPCs in this Group are small, most are. About two-thirds of the NPCs in this group reported less than $1 million in 2016 revenue.**
- **The 35 NPCs in this group collectively reported $43.7 in revenue in 2016, or approximately 16 percent of the revenue reported by all 83 NPCs in 2016.**

Interviewees sometimes described differences in policy versus practice at locations that have a formal policy or informal guidelines regarding extramural grant submission.

Interviewees at several VAMCs with policies (Group 1) or informal guidelines (Group 2) told us that, in practice, PI's have a great deal of leeway to decide which organization –the NPC or affiliate –they will use to submit and ultimately manage their projects, policies or guidelines notwithstanding:

> *"I personally don't know of the existence of an MOU. I know of a general policy…nothing written... In theory, [the NPC has] the right of first refusal. But in reality…all the NIH grants and DOD are usually run by the affiliate. Even if a researcher who's dually appointed at [the VAMC] and also at [the academic affiliate], if that person wins a grant or prepares a grant and the work is going to be done at VA, currently it's most likely that it would be administered at [the affiliate]."*
> –ACOS for Research, VAMC in Group 2

> *"The bottom line is that PIs are free to go in either direction, depending on what they want to do. And in the case of department of medicine, they're being pressured to go to the affiliate."*
> –ACOS for Research, VAMC in Group 1

Some interviewees felt that, although their VAMC does have a written policy or informal procedures directing grant administration, differences in policy versus practice occur because enforcement of the policy is lacking:

> *"There has to be more pressure from the top to utilize NPCs."*
> –ACOS for Research, VAMC in Group 2

> *"[The policy is followed] half the time, or less than half the time."*
> –Executive Director of NPC in Group 1

Several interviewees told us that NPCs would benefit from a greater emphasis—either from VA headquarters in Washington or from the leadership of their VAMC—on enforcement of existing policies or procedures:

> *"The real key is that the SOP has to have teeth, which means the R&D Committee has to be willing to not approve a project if it's inappropriately submitted through the university."*
> –Executive Director of NPC in Group 1

> *"So, the [preponderance] rule—it's understood that if the research project is done [more than 50%] at the VA, it should be administered by the NPC...But there is no enforcement, and this enforcement should come from D.C., not from the Medical Center."*
> –Executive Director of NPC in Group 1

Interviewees gave mixed perspectives on the need for greater formalization and enforcement of policies regarding grant administration for VA extramural research.

For some interviewees, particularly those working at sites that lacked policies or who described a difficult relationship with their academic affiliate, the implementation and enforcement of a policy governing grant submissions by dual appointed VA investigators was much desired. These interviewees explained clear policy is needed to reduce conflicts of interest resulting from the fact that dual appointed investigators have two employers, or to prevent what they view as academic affiliates taking advantage of VA or the NPC:

> *"The university is getting the benefits of all the overhead, yet we're doing most of the support work at the VA…I think there should be a policy between the university and the VA that states when the PI is intending to do a majority of work at the VA, that the grant should be submitted through the NPC."*
> –ACOS for Research at VAMC in Group 3

> *"VA should take a stand and say 'if the work is being done at the VA, then the particular portion of that work needs to be administered by the nonprofit."*
> –Executive Director of NPC in Group 1

> *"I would be in favor of a system that says: 'we're going to be governed on the distribution of the dollars by where the percentage of the work that's being done.'…That would feel really fair to me. [Right now] we don't have access to the NIH grants…It locks us out, and then we get a small percentage of that money…It's kind of decided politically two or three or four levels above us."*
> –Executive Director of NPC in Group 2

Not all interviewees, however, shared the view that VA research would benefit from a strict enforcement of polices, particularly a blanket policy covering all VAMCs. At some locations, ACOSs expressed concern that rigorous enforcement of a standard set of rules for dual appointed VA investigators could lead to a loss of talented staff, or strain relations with the academic affiliate, resulting in a loss of access to resources or academic career benefits for PIs. In their view, VA research could be an unintended casualty of any VA-mandated policy directing PIs to bring their federal grants through the NPC:

> *"It is important to stress that we have a very good relationship with our affiliate, and I think both parties have benefited tremendously by [our] interaction…It's very important to make sure that any sort of new policy [doesn't] infringe upon that, or reduce the potential for something that is very strong already."*
> –ACOS for Research at VAMC in Group 2

"I think we really need concrete rules and policies of how these funds are going to be administered. [But] we have to be careful these rules are not too rigid, because…the recruitment of successful investigators requires both [VA and Affiliate] involvement, and therefore if we become too harsh in our policies, it might ruin our ability for recruitment of good investigators."
–ACOS for Research at VAMC in Group 2

I think each [VA-affiliate] partnership needs some leeway toward [working out] these relationships on their own…I do agree with the premise that it shouldn't be left up to individual PIs to make [the grant submission decision, but]…The VA jointly recruits faculty with the university. We have residents and a stream of physicians that come to us from the university, so I wouldn't want the applecart turned over because of something like this."
–ACOS for Research at VAMC in Group 1

Similarly, we heard from several ACOSs that there was a risk of academic affiliates withdrawing support or reducing their collaboration with the VAMC if dual appointed investigators were directed to submit their NIH grants through the NPC. Along these lines, some of the interviewees suggested the PIs themselves would face a difficult choice whether to remain with VA or work full time for the affiliate if they lost their autonomy:

"[We have to] incentivize investigators as much as possible to come to the VA and do research...if we forced VA investigators to obtain their extramural funding, for example, through the non-profit, many of them would say, 'the heck with that, I'm leaving.'"
–ACOS for Research at VAMC in Group 3

"Having a group of well-known scientists involved in your project counts, and our affiliation…I'm not going to say that this would completely disappear if all of a sudden we brought our NIH grants to our nonprofit, but I'm saying that it would seriously harm what is a strong and effective affiliation."
–ACOS for Research at VAMC in Group 2

Some interviewees provided a contrasting view, explaining that while VAMCs gain many benefits from their relationship with affiliates, such as high quality research staff and clinical care provided by residents and medical students, the affiliates benefit to an equal degree through access to the VA patient population for training and research. These interviewees suggested that if a policy like the preponderance rule was applied to all funding sources, dual appointed PIs and affiliates would ultimately make the adjustment after a period of resistance, or in some cases, have already done so:

"We [the VA and affiliates] need each other...You're going to have lot of [PIs], once they start actually working with the nonprofit, they're going to [want to] work with the nonprofit."
–Executive Director of NPC in Group 1

"[Several years ago] there was a lot of pushback by the university because they were losing all the indirects that were now…going to the NPC. But now…that has all settled down. There's peace now."
–ACOS for Research at VAMC in Group 1

Summary for Questions 2, 2(a) and 7

- There is no single policy across VAMCs that addresses the issue of where VA investigator grants should be managed and under what conditions. Executive Directors of NPCs and ACOSs described a range of approaches regarding how the VAMC approaches grant administration decisions.
- Based on interviews with more than 140 stakeholders at 78 VAMCs/NPCs, we found that the VAMCs tend to fall into one of three groups with respect to submission policies applicable to VA investigator grants. These groups are:
  - VAMCs with formal written policies (23 of 78)
  - VAMCs with unwritten informal guidelines (20 of 78)
  - VAMCs without a policy or guidelines and where PIs make the decision (35 of 78)
- The most common policy criterion in use among VAMCs with a written policy was the "preponderance rule." This rule designates the NPC as the appropriate organization through which a PI should submit a grant if the majority of work will be performed at VA. Exceptions require review and authorization by a person or committee providing oversight for the VAMC.
- VAMCs with informal guidelines most commonly used some version of the preponderance rule as the basis of their grant submission guidelines.
- Several sites have policies or guidelines that specify that NIH grants, or sometimes all federal grants, will be administered by the academic affiliate. Many interviewees at these locations expressed that this negotiated arrangement ensures productive and mutually beneficial relations with the affiliate.
- At VAMCs with written policies or guidelines, interviewees often described examples in which actual practices differed from the policy. The most common example involved PIs submitting federal grants through the affiliate when policy or guidelines stipulate otherwise.
- Interviewees gave mixed perspectives on the need for greater formalization and enforcement of policies regarding grant administration for VA extramural research.
- Some interviewees believed a consistent policy, or better enforcement of existing policies, is needed to ensure VA investigators utilize the NPCs and submit extramurally funded grants through them when their work is conducted principally at VA. This could reduce potential conflicts of interest for dual appointed staff, and generate more resources for VA research.
- Other interviewees expressed concern that a "one size fits all" policy, or any policy that lacks flexibility or is too rigorously enforced, could damage the VA research mission—and potentially clinical care at VA hospitals—by reducing the affiliates' desire to collaborate and share resources, or through the loss of talented research scientists and clinicians to the university.

Q3. How are NIH grant funds administered?

Q3a. If the majority of the work (i.e. greater than 50 percent) is done at the VA, does the NPC administer the funding?

The RDIS database contains details on the research expenditures from VA related research. VA PIs report basic project information along with grant funding sources, the entity that administered grant funds, the percentage of project research performed at the VA, and the amount expended from the grant in the fiscal year. In the large majority of cases, either an NPC or an academic affiliate administers extramurally funded research, including NIH funded projects. In order to answer how NIH grant funds are administered, we analyzed all entries in the RDIS database between 2014 and 2016 that met the following three criteria:

- NIH or one of its component institutes was listed as the funding source;
- An NPC or an academic affiliate served as prime; and[19]
- The research was performed by an investigator associated with a VAMC that has an affiliated NPC.[20]

Using these criteria, we examined the distribution of NIH funding and grant administration across NPCs and academic affiliates, both at the overall level and the level of individual VAMCs and their NPCs.

The number of NIH grants and annual NIH funds expended during 2014-2016 are displayed in Table 3-4. The table shows that the overall number of NIH grants declined each year during this period from a high of 1,531 in 2014 to a low of 1,388 in 2016. This was matched by a decline in expended NIH funds from around $338 million in 2014 to $280 million in 2016. The table also shows that academic affiliates managed a much larger number of grants and a larger share of NIH funding than NPCs during this period. NPCs managed between 494 and 534 NIH grants annually during the period, compared 894 to 1007 for the affiliates. Even though overall funding from NIH

[19]Projects listed as managed by an organization other than an NPC or an academic affiliate were not included in the analysis. Examples would include projects listed as being managed by the VAMC.

[20]A small number of VAMCs do not have an affiliated NPC. Projects conducted at these VAMCs were not included in the analysis.

dropped significantly from 2014 to 2016, the share of NIH funds managed by NPCs increased somewhat during the period, from approximately 27 percent in 2014 to 29 percent in 2015 and 2016.

Table 3-4. All NIH grants and expenditures, by year and administrative location*

Administrative entity	Number of NIH grants			NIH Funds expended		
	2014	2015	2016	2014	2015	2016
NPC	534 (35%)	547 (37%)	494 (36%)	$89,797,181 (27%)	$85,537,321 (29%)	$79,980,909 (29%)
Academic Affiliate	1,007 (65%)	925 (63%)	894 (64%)	$247,737,776 (73%)	$212,043,302 (71%)	$200,382,283 (71%)
Total	**1,541 (100%)**	**1,472 (100%)**	**1,388 (100%)**	**$337,534,957 (100%)**	**$297,580,623 (100%)**	**$280,363,192 (100%)**

*Only prime awards are included, to avoid double counting.

If the majority of the work (i.e., greater than 50 percent) is done at the VA, does the NPC administer the funding?

RDIS data include an estimate from VA PIs on the share of their research that takes place at the VA. We used this information to examine whether NIH grants performed primarily or fully at VA are administered by the NPCs or by academic affiliates. Table 3-5 displays all NIH grants performed and all NIH funding expended by VA investigators during 2014-2016, and whether those grants and expenditures were conducted predominately at VA or otherwise. The table also shows, for each of these two workshare conditions, the amount of grants and funding administered at the prime level by NPCs versus academic affiliates. The RDIS data shown in Table 3-5 indicate that, although NPCs do not always administer the funding for NIH grants performed predominately at VA, they substantially increased the share of such funding that they administered between 2014 and 2016.

Table 3-5. NIH grants and expenditures by share of work conducted at the VA, prime awardee, and year*

	Number of NIH grants			NIH funds expended		
	2014	2015	2016	2014	2015	2016
NIH grants in which the majority of work is conducted at VA						
Administered by NPCs	424 (49%)	420 (54%)	384 (52%)	$80,534,621 (47%)	$75,237,110 (55%)	$71,824,030 (56%)
Administered by Affiliates	434 (51%)	363 (46%)	349 (48%)	$91,402,616 (53%)	$65,089,503 (45%)	$57,347,867 (44%)
Total	**858 (100%)**	**783 (100%)**	**733 (100%)**	**$171,937,237 (100%)**	**$140,326,613 (100%)**	**$129,171,897 (100%)**
NIH grants in which 50% or less of work is conducted at VA						
Administered by NPCs	110 (16%)	127 (18%)	110 (17%)	$9,262,560 (6%)	$10,300,211 (7%)	$8,156,879 (5%)
Administered by Affiliates	573 (84%)	562 (82%)	545 (83%)	$156,335,160 (94%)	$146,953,798 (93%)	$143,034,415 (95%)
Total	**683 (100%)**	**689 (100%)**	**655 (100%)**	**$165,597,720 (100%)**	**$157,254,009 (100%)**	**$151,191,294 (100%)**

*Only prime awards are included, to avoid double counting.

Table 3-5 shows that the large majority of revenue managed at the prime level by academic affiliates is for projects in which less than half the work is conducted at VA, but that academic affiliates also manage significant funding for projects in which the preponderance of work is performed at VA. For example, in 2014 academic affiliates managed $91.4 million worth of NIH-funded grants in which the preponderance of work occurred at VA. This total was about $11 million higher than the prime funding NPCs managed in 2014 for NIH grants performed predominately at VA.

In 2015 and 2016 however, the amount of funding managed by the NPCs for grants performed predominately at VA exceeded that managed by the affiliates. This occurred not because NPCs increased their prime NIH funding during those years, but because the amounts managed by the affiliates fell drastically, corresponding with the overall drop in NIH funding shown earlier in Table 3-4. Affiliate-managed funding for work performed mostly at VA dropped 37 percent between 2014 and 2016 ($91 million to $57 million). Funding managed at the prime level by the NPCs for these grants declined also over the same period, but not nearly as steeply ($80.5 million to $71.8 million, or 11%). In 2015, NPCs managed more than $75 million in NIH funded projects conducted primarily at the VA, whereas affiliates managed roughly $65 million. In 2016, NPCs managed approximately $72 million in funding for grants performed mainly at VA, compared with $57 million managed by the affiliates. NPCs therefore increased their share of NIH funding compared with affiliates over the three-year period.

With respect to NIH funded VA-involved grants that are not performed predominately at VA, academic affiliates administer the lion's share of funding on behalf of VA PIs. In 2016 for example, affiliates managed $143 million in NIH grants in which half or less of the work was performed at VA, whereas NPCs administered only about $8 million of prime funding for such projects. These types of grants—i.e., those not performed predominately at VA—made up only 10-12 percent of NIH prime funding under management at NPCs during 2014-2016.

The Role of NPC Size in Understanding How VA-Related NIH Grants are Managed

While the previous tables showed that NPCs increased their share of grant funding relative to the academic affiliates from 2014 to 2016 for projects conducted predominately at VA, this funding is heavily concentrated among the largest NPCs. Table 3-6 displays the number of NIH grants and associated expenditures during 2014-2016 for five groups of NPCs of different sizes. The table, which includes only NIH grants performed predominately at VA, also displays the number of grants and expenditures managed by the respective academic affiliates. To create the NPC size groupings, we used the amount of each NPC's 2016 annual revenue from all grants and projects as listed in their Annual Report to VA.

Table 3-6. NIH grants at VAMCs with an affiliated NPC when the majority of work is conducted at the VA, by NPC size and year

NPC size (2016)	No. of NPCs	Administrative entity	Number of NIH grants			NIH funds expended		
			2014	2015	2016	2014	2015	2016
$4M & Above	13	NPC	307	308	304	$72,246,722	$68,039,183	$65,291,056
		Academic Affiliate	144	148	143	$43,743,666	$25,895,565	$24,700,872
$2M – $4M	18	NPC	49	51	41	$4,178,890	$4,342,661	$4,482,428
		Academic Affiliate	108	87	76	$17,119,123	$17,740,353	$12,673,504
$750K – $2M	21	NPC	58	49	33	$3,100,302	$1,851,381	$1,421,890
		Academic Affiliate	118	77	95	$20,620,118	$10,311,717	$12,557,356
$250K – $750K	17	NPC	10	12	6	$1,008,708	$1,003,885	$628,656
		Academic Affiliate	58	48	32	$9,378,567	$9,934,606	$6,716,388
Below $250K	14	NPC	0	0	0	$0	$0	$0
		Academic Affiliate	6	3	3	$541,142	$1,207,263	$699,748
Total	**83**		**858**	**783**	**733**	**$171,937,237**	**$140,326,613**	**$129,171,897**

The table shows that, in 2104, the largest 13 NPCs (those with $4 million or more in annual revenue) accounted for more than $72 million (90%) of the total $80.5 million in NIH grant funding managed by all 83 NPCs for projects conducted predominately at VA. The share of funding

managed by this group of large NPCs remained constant in 2014 and 2015, at around 90 percent. This group of large NPCs is also the only size group in which the amount of NIH funding under management for these types of grants exceeds that managed by their affiliates. For the 70 NPCs not in the largest category, the academic affiliates manage the vast majority of NIH funded grants and associated expenditures when the research is performed at the VA. The smallest group of NPCs, those with revenue under $250,000 in 2016, had no NIH-funded grants under management from 2014-2016.

Summary for Questions 3 and 3(a)

- During 2014-2016, VA investigators worked on an average of 1467 NIH grants per year. NPCs administered slightly more than one-third of these grants. Academic affiliates managed the rest.
- VA PIs reported expending $337.5 million in NIH grant funding in 2014, $297.5 million in 2015 and $280.3 million in 2016. NPCs managed between 27 and 29 percent of this funding, depending on the year. Academic affiliates managed the remainder.
- Between 2014 and 2016, NPCs collectively increased their share of NIH prime funding under management for VA investigator grants performed predominately at VA. The share of this funding managed by NPCs rose from 46.8 percent in 2014 to 55.6 percent in 2016.
- The increase in the NPCs' share of prime funding relative to academic affiliates has taken place at the same time in which the overall amount of NIH funding expended for VA extramural research declined substantially. The increase in the NPCs' share of prime funding is not due to an increase in their NIH revenue, but rather to a significant decline in NIH funding managed by the affiliates for work performed predominately at VA.
- The 13 largest NPCs—those with more than $4 million in 2016 revenue—administer a disproportionate share of all the NIH funding managed by NPCs. NPCs in this largest size category administered roughly 90 percent of the NIH prime funding under management by all the NPCs during 2014-2016.
- For the 70 NPCs with revenues less than $4 million, the academic affiliates are much more likely to administer the NIH grants of VA investigators, even if most or all the work is performed at VA.
- NPCs administer a very minor share of NIH funded VA investigator grants in which the majority of work is not performed at VA. The share of funding for grants of this type managed by NPCs was in the 5-6 percent range during 2014-2016.

Q4. How much research supported by NIH is conducted solely at the VA, and how much is spent in collaboration at the university?

Q5. How many of the NIH-granted funds are spent solely at the VA?

Q5a. How much is spent in collaboration with the university?

Questions 4, 5 and 5(a) address the overall number and funding amounts of NIH grants performed by VA investigators, with a specific focus on understanding the proportion of grants and funding performed exclusively at VA versus in collaboration with academic affiliates. Since these questions have a similar focus, we present the findings collectively in this section.

To determine the number of distinct NIH grants and the total amount of NIH funds expended solely at the VA versus collaboratively with academic affiliates, we used data from the RDIS database. The database contains a field in which each PI reports, for each grant year, the percentage of project expenditures taking place at VA. To answer the research questions above, we reviewed and analyzed all grant entries in the RDIS database between 2014 and 2016 that met the following criteria:

- NIH or one of its component institutes was listed as the funding source.
- An NPC or an academic affiliate served as prime.[21]
- The research was performed by an investigator associated with a VAMC that has an affiliated NPC.[22]

This is the same set of NIH grants we analyzed to answer Research Questions 3 and 3(a). We assigned each NIH grant that met the eligibility criteria to one of two groups: (1) grants coded by the PI as performed solely at VA (100%), and (2) grants in which less than 100 percent of the work was

[21]Projects listed as managed by an organization other than an NPC or an academic affiliate were not included in the analysis. Examples would include projects listed as managed by a VAMC directly.

[22]A small number of VAMCs do not have an affiliated NPC. Projects conducted at these VAs were not included in the analysis.

performed at VA. For the purpose of our analysis, we consider any NIH grant not conducted 100 percent at the VA as a collaborative effort with the academic affiliate.[23]

We present the number of NIH grants performed by VA investigators between 2014 and 2016, and the expended funds associated with these grants, in Table 3-7. The table shows that, in each of the three years considered, grants expended solely at VA account for roughly half the total number of grants. The ratio of grants performed solely at VA versus in collaboration with the affiliate remained relatively constant over the three-year period, although the overall number of grants performed by VA investigators declined each year, from 1541 in 2014 to 1388 in 2016.

Table 3-7. NIH grants and expenditures, by year and collaboration status*

Location of work	Number of NIH grants			NIH funds expended		
	2014	2015	2016	2014	2015	2016
100% at the VA	774 (50%)	711 (48%)	668 (48%)	$157,815,240 (47%)	$124,798,696 (42%)	$115,532,644 (41%)
Less than 100% at the VA	767 (50%)	761 (52%)	720 (52%)	$179,719,717 (53%)	$172,781,927 (58%)	$164,830,548 (59%)
Total	**1,541 (100%)**	**1,472 (100%)**	**1,388 (100%)**	**$337,534,957 (100%)**	**$297,580,623 (100%)**	**$280,363,192 (100%)**

*Only prime awards are included, to avoid double counting.

With respect to funding expended, the table shows a significant overall decline in total NIH funding expended by investigators between 2014 and 2016; this decline was noted earlier in the discussion of Research Question 3. The table also shows there was a slight increase, year after year, in the share of NIH funds expended on collaborative projects compared to projects solely conducted at VA. Specifically, collaborative projects accounted for 53 percent of all funding in 2014 and rose to 59 percent in 2016. In other words, although overall NIH funding for both kinds of projects declined from 2014 to 2016, funding for projects conducted solely at VA declined at a steeper rate (29%) than collaborative projects (9%) over the same period.

[23] Although VA researchers occasionally conduct NIH-funded collaborative projects with other organizations besides universities, the vast majority of such projects are collaborations with academic affiliates. RDIS data indicate that 94 percent of funds expended in collaborative projects during 2014-2016 are administered by academic affiliates.

The Role of NPC Size in Understanding Collaborations on Veteran-Involved NIH Grants

As highlighted in the discussion of Research Question 3, NIH funded grants conducted by VA investigators are heavily concentrated at VAMCs that host large NPCs. Table 3-8 shows the number of NIH grants and the amount of NIH funding expended at locations that host NPCs of different sizes, exclusive of whether the NPC or affiliate manages the work. The table also displays, for each size category, whether the grants and associated funding are spent solely at VA or in collaboration with the affiliate.

Table 3-8. VA-involved NIH grants and funding, by NPC size, year and collaboration status

NPC size (2016)	No. of NPCs	Location of work	Number of NIH grants			NIH Funds expended		
			2014	2015	2016	2014	2015	2016
$4M & Above	13	100% at the VA	416	431	420	$110,350,533	$88,531,816	$84,008,428
		Less than 100% at the VA	159	141	136	$36,420,700	$35,939,163	$34,701,420
$2M – $4M	18	100% at the VA	138	121	105	$18,010,632	$17,619,466	$15,451,272
		Less than 100% at the VA	325	315	257	$64,377,835	$54,873,197	$43,830,687
$750K –$2M	21	100% at the VA	160	114	108	$19,839,449	$10,653,074	$9,708,133
		Less than 100% at the VA	156	173	183	$43,095,309	$44,417,193	$45,203,394
$250K – $750K	17	100% at the VA	54	43	32	$9,073,484	$7,012,077	$5,665,063
		Less than 100% at the VA	117	119	127	$27,927,785	$29,621,138	$31,706,184
Below $250K	14	100% at the VA	6	2	3	$541,142	$982,263	$699,748
		Less than 100% at the VA	10	13	17	$7,898,089	$7,931,236	$9,388,862
Total	**83**		**1,541**	**1,472**	**1,388**	**$337,534,957**	**$297,580,623**	**$280,363,192**

Depending on the year, between 37 percent and 40 percent of all NIH grants awarded to VA investigators were expended at the 13 locations that host NPCs with more than $4 million in annual revenue. Similarly, these locations account for approximately 43 percent of all NIH funding expended by VA PIs between 2014 and 2016.[24] At these 13 locations, the large majority of the work performed each year was conducted solely at the VAMC. For example, in 2014, more than 75 percent of the $146.8 million in NIH funding received at these 13 locations was expended entirely at VA. In both 2015 and 2016, 71 percent of NIH funding expended at these locations was for projects performed solely at VA.

For all other size groups (i.e., locations that host medium-sized or smaller-sized NPCs), the pattern is reversed, with funding amounts for collaborative projects much greater than funding for projects

[24]These percentages are not shown in the table so as not to increase the table's complexity.

performed solely at the VA. In other words, for VAMCs that host NPCs with less than $4 million in annual revenue, the majority of NIH grants and NIH funding is expended in collaboration with the affiliate. For example, at the 18 VAMCs that host an NPC with annual revenue between $2 million and $4 million, only about 22 percent of the total NIH funding expended in 2014 was for projects performed solely at VA, with the balance of funding (78%) being utilized in collaboration with affiliates. In 2015 and 2016, roughly one-fourth of NIH funding at these locations was expended for projects performed solely at VA, with about three-fourths expended for collaborative projects.

At VAMCs that host the smallest 14 NPCs (those with under $250,000 in 2016 revenue), the share of NIH grant funding expended for projects performed solely at VA was relatively small. In 2014, approximately 6 percent of NIH funding expended by PIs at these locations was for projects conducted exclusively at VA, with 94 percent expended for projects conducted in collaboration with the affiliate. In 2015, 11 percent of NIH funding at these sites was expended for grants performed solely at VA, and in 2016, the share for projects performed exclusively at VA was 7 percent. As noted in the discussion of Research Question 3, NPCs with less than $250,000 in 2016 revenue did not administer an NIH grant during the period 2014 through 2016, so all of the NIH funding expended by PIs through the NPC at these locations was via subawards from affiliates.

Summary for Questions 4, 5 and 5(a)

- **Slightly less than half of NIH grants performed by VA investigators are for projects where work is conducted solely at VA. The share, by year, of NIH grants performed solely at VA was 50 percent in 2014, 48 percent in 2015 and 48 percent in 2016.**
- **Between 2014 and 2016, there was an overall decrease in the total number of NIH grants performed by VA investigators. During this period, the share of grants performed in collaboration with academic affiliates increased slightly, from 50 percent in 2014 to 52 percent in 2016.**
- **NIH grants where work is conducted solely at VA are concentrated at locations that host the largest NPCs (i.e., those with more than $4 million in 2016 revenue). Approximately 28 percent of all NIH funded grants conducted solely at VA were performed at these 13 locations.**
- **For VAMCs that host an NPC with less than $4 million in revenue, it is much more common for grants to be performed in collaboration with the affiliate rather than exclusively at VA.**
- **Most NIH funding expended by VA investigators is spent on grants performed collaboratively (i.e., where less than 100 percent of the work is performed at VA). The share of expenditures for collaborative projects, as compared to projects conducted solely at VA, increased from 53 percent in 2014 to 59 percent in 2016.**

Q5b. Is the NPC a subcontractor on work done at the VA?

The study team asked interviewees at all 78 locations if—in cases where the affiliate manages the grant of a dual appointed VA investigator and some or all of the work is performed at the VAMC or NPC—the NPC is awarded a subcontract or subaward to cover costs of the portion of work performed at VA.[25] **At most locations, interviewees told us that under those circumstances, a subaward was common practice and happens more or less consistently:**

> *"So most of our DOD-funded projects have been subcontracts…though most of the overall project is being conducted at [the affiliate], investigators will want to also recruit from the VA."*
> –ACOS for Research at VAMC in Group 1

> *"…It's not a contentious issue here…even if something is administered at the university…If a portion of that [grant] is done at our institution, we [receive] subawards, and we would get our indirect costs applied to the subawards."*
> –Executive Director of NPC in Group 2

At roughly one-third of VAMCs/NPCs however, interviewees explained that the affiliate, acting as prime, does not always provide a subaward to the NPC:

> *"It could be [that the NPC receives a subaward], but that would be a very rare occasion."*
> –ACOS for Research at VAMC in Group 2

> *"Sometimes, yes [the NPC receives a subaward]. Sometimes when it's appropriate. I want to point out, though, we have no way of knowing if somebody's doing work on an NIH grant at our facility unless they tell us."*
> –Executive Director of NPC in Group 1

> *"Not always. They [PIs] are able to come over here and conduct research on the VA population without it going through us."*
> –Executive Director of NPC in Group 3

> *No, we don't [receive a subaward for work performed at VA]. And that's been an issue with NIH."*
> –ACOS for Research at VAMC in Group 2

[25]Subawards to the NPC from academic affiliates are accompanied by payments of indirects to the NPC.

A few interviewees described administrative mechanisms, such as the Work Without Compensation appointment (WOC), that are negotiated by the VAMC and the affiliate to allow grant work to be performed at VA without the need for a subaward to the NPC:

> *"…[The affiliate] is able to send over [it's] own university people, paid for by the grants, and there's no proper routing of that money…so instead of the non-profit hiring the person, the university hires them on the grant and sends them over [to VA] on this thing called a without compensation or WOC appointment."*
> –Executive Director of NPC in Group 3

Some interviewees who told us that subawards were not always issued by the affiliate described other mechanisms that were in place between the VAMC and the affiliate to ensure that VA recaptured some of the costs associated with grant performance. These mechanisms included periodic payments from the university to the VAMC, or billing the university for the PI's use of certain VA resources:

> *"[We receive subawards] sometimes. Again, part of the reason I say sometimes is that we do have this shared clinical research unit and we are reimbursed. We, meaning our VAMC, is reimbursed for the use of that unit by the grants that the investigators have at the university."*
> –ACOS for Research at VAMC in Group 3

> *I just negotiated [an arrangement with the affiliate] last year [whereby] $50,000 a year for three years is put into a fund called the VA Research Development Fund… it's university money…and that was their acknowledgment that, 'yes, we aren't giving you anything back from all the indirects even though most of the research happens at the VA."*
> –ACOS for Research at VAMC in Group 1

Summary for Question 5b

- **A majority of interviewees explained that when the affiliate manages the grant of a dual appointed VA investigator, and some or all of the work is performed at the VA, the NPC is awarded a subcontract/subaward to cover the costs of the work performed at VA.**
- **At roughly one-third of VAs/NPCs, interviewees noted that the affiliate, when acting as prime, does not always provide a subaward to the NPC even when work is conducted at the VA.**
- **At some NPCs that do not receive subawards from the affiliate for work conducted at the VA, the affiliate and the VAMC have an alternate arrangement to recapture costs associated with grant performance.**

Q6. When funding is received at the university, where is the research conducted?

Consistent with the approach used in previous sections, to answer Research Question 6 we identified all grants entered by PIs in the RDIS database that met these three criteria:

- An extramural funder was listed as the funding source.
- An academic affiliate served as prime.
- The research was performed by an investigator associated with a VAMC that has an affiliated NPC.[26]

Table 3-9 shows the distribution of all grants performed by VA investigators and administered by academic affiliates during 2014-2016, by the percentage of work conducted at VA. The table indicates that, depending on the year, between 37 percent and 41 percent of the grants administered by affiliates were conducted at both the university and VA. Slightly more than one-third of grants in each year were conducted solely at VA, and about one-fourth were conducted solely at the university. Less than half of affiliate-managed grants were conducted mostly or exclusively at VA in each year.

Table 3-9. Extramural grants administered by affiliates, by year and share of work performed at VA*

	2014	2015	2016
100% performed at the VA	562 (37%)	471 (34%)	487 (36%)
Between 51% and 99% performed at the VA	107 (7%)	106 (8%)	87 (6%)
From 1% to 50% performed at the VA	458 (30%)	451 (33%)	430 (32%)
0% performed at the VA	376 (25%)	357 (26%)	336 (25%)
Total	**1,503 (100%)**	**1,385 (100%)**	**1,340 (100%)**
Share of affiliate-managed grants performed mostly or fully at VA	44.5%	41.6%	42.8%

*Table includes extramural grants from all sources. Percentages may not sum to exactly 100 due to rounding.

[26]A small number of VAMCs do not have an affiliated NPC. Projects at these VAs were not included in the analysis.

Table 3-10 presents the distribution of these affiliate-managed grants by NPC size (defined by 2016 revenue) and by the share of work performed at the VA. The table shows that, when affiliates are managing grants at locations that host the largest NPCs, most of those grants are for projects in which the preponderance of work occurs at VA. For example, in 2016, affiliates administered 390 grants at locations that host the largest 13 NPCs. Of those 390 grants, 227 (58%) funded projects conducted mostly or fully at VA. It is important to note, however, that this is in addition to the more than 300 NIH prime awards that NPCs in this size category collectively administered themselves during 2016 (shown earlier in Table 3-6).

Table 3-10. Extramural Grants Administered by Affiliate, by NPC size, year, and by share of work performed at VA*

NPC size (2016)	No. of NPCs	Location of work	2014	2015	2016
$4M & Above	13	100% performed at the VA	163	186	196
		Between 51% and 99% performed at the VA	40	31	31
		From 1% to 50% performed at the VA	124	111	119
		0% performed at the VA	28	28	44
$2M –$4M	18	100% performed at the VA	134	120	97
		Between 51% and 99% performed at the VA	26	26	9
		From 1% to 50% performed at the VA	111	127	75
		0% performed at the VA	208	193	182
$750K –$2M	21	100% performed at the VA	169	107	138
		Between 51% and 99% performed at the VA	20	16	23
		From 1% to 50% performed at the VA	112	97	112
		0% performed at the VA	82	98	71
$250K –$750K	17	100% performed at the VA	90	56	53
		Between 51% and 99% performed at the VA	20	31	24
		From 1% to 50% performed at the VA	110	115	118
		0% performed at the VA	41	27	28
Below $250K	14	100% performed at the VA	6	2	3
		Between 51% and 99% performed at the VA	1	2	0
		From 1% to 50% performed at the VA	1	1	6
		0% performed at the VA	17	11	11
Total	**83**		**1,503**	**1,385**	**1,340**

*Table includes extramural grants from all funding sources.

The table also shows that, at locations hosting NPCs outside of the largest size category, affiliate managed grants are more likely to be projects in which the preponderance of work does not occur at VA. For example, at locations hosting NPCs with 2016 revenue between $750,000 and $2 million, affiliates managed 344 grants in 2016. Less than half of those grants (47%) funded projects in which the majority of work was performed at VA.

Summary for Question 6

- When prime funding is received by the university to support VA investigators, the work is most frequently conducted collaboratively, at both at VA and at the affiliate.
- The majority of grants administered by academic affiliates on behalf of VA investigators support projects in which the preponderance of work (more than 50%) does not occur at the VA.
- A sizable share, however, (between 42% and 45%, depending on the year) of affiliate-managed grants do fund work conducted mostly or fully at VA.
- There is variation in where the work is conducted when the university manages a VA investigator's grant, based on the size of the NPC. At locations that host the largest NPCs by revenue, affiliate-managed grants tend to support projects in which the preponderance of work is conducted at VA. At all other locations (i.e., those hosting NPCs not in the largest size category), affiliate-managed grants tend to support projects in which the preponderance of work does not occur at VA.

Q6a. What kinds of research are conducted?

To address this question, we reviewed the funding source of the affiliate-managed extramural grants from 2014-2016, using information contained in the RDIS database. We also reviewed and analyzed the descriptive data used by PIs to describe their research within RDIS. (Our approach to the descriptive analysis is presented in the methodology chapter). Below we present findings regarding the funding sources and topics of research conducted by VA investigators whose grants are administered by academic affiliates.

Table 3-11 presents the distribution, by funding source, of all affiliate-managed grants performed by VA investigators between 2014 and 2016. The primary funding source for affiliate-managed grants was NIH, which accounted for two-thirds of all affiliate-managed grants during each year. However, academic affiliates also administered funds from other federal agencies such as DOD, as well as funds from state and local government agencies, private donors, private companies and non-profit agencies or foundations.

Table 3-11. Extramural grants administered by academic affiliates, by funding source

	Total		
	2014	2015	2016
NIH grants	994 (66%)	918 (66%)	885 (66%)
Other Federal Government Agency Grants	146 (10%)	136 (10%)	130 (10%)
Other government or private donors	88 (6%)	68 (5%)	71 (5%)
Private Proprietary Company Grants	107 (7%)	100 (7%)	82 (6%)
Voluntary Agency or Foundation Grants	168 (11%)	163 (12%)	172 13%)
Total	**1,503 (100%)**	**1,385 (100%)**	**1,340 (100%)**

Hundreds of medical researchers with full-time or part-time appointments at VA conduct hundreds of studies each year on an extraordinary range of health issues and conditions that affect the lives of Veterans. While it is beyond the scope of this report to present a comprehensive review of current and recent research conducted to improve Veteran health and care,[27] we conducted an analysis of

[27]For up-to-date and detailed information describing the breadth and impact of VA medical research, the VA's Office of Research and Development (ORD) maintains a website devoted to this topic at: https://www.research.va.gov/

the key descriptive terms entered in the RDIS database and used by VA investigators to describe their affiliate-administered grants. Table 3-12 presents the results of this analysis of descriptive keywords. Based on the frequency of these terms, affiliate-managed grants are supporting multiple VA research studies in the areas of cancer, aging, heart disease, alcohol, diabetes, HIV, prostatic and kidney disease, to list just a few of the most common topics. The frequency with which PIs used descriptive terms such as 'brain' and 'Veteran' suggest that affiliate-managed projects support research applicable to VA priority areas, such as brain injuries. Additionally, the frequency of 'clinical' in the list of keywords suggests affiliate-managed projects are helping Veterans gain access to extramurally funded clinical trials and research.

Table 3-12. Most common keywords used by VA PIs in research administered by academic affiliates*

	2014		2015		2016	
Disease	168	(2.4%)	154	(2.4%)	179	(2.9%)
Cancer	97	(1.4%)	102	(1.6%)	94	(1.5%)
Cells	91	(1.3%)	72	(1.1%)	67	(1.1%)
Research	60	(0.9%)	73	(1.1%)	79	(1.3%)
Aging	69	(1.0%)	71	(1.1%)	73	(1.2%)
Diabetes	80	(1.1%)	63	(1.0%)	54	(0.9%)
Injury	78	(1.1%)	71	(1.1%)	62	(1.0%)
Heart	57	(0.8%)	66	(1.0%)	36	(0.6%)
Disorders	66	(0.9%)	65	(1.0%)	59	(1.0%)
Kidney	70	(1.0%)	61	(0.95%)	55	(0.9%)
Veterans	55	(0.8%)	65	(1.0%)	62	(1.0%)
Brain	65	(0.9%)	60	(0.9%)	59	(1.0%)
Therapy	53	(0.8%)	55	(0.9%)	38	(0.6%)
Drug	55	(0.8%)	38	(0.6%)	37	(0.6%)
HIV	53	(0.8%)	51	(0.8%)	47	(0.8%)
Failure	44	(0.6%)	50	(0.8%)	26	(0.4%)
Alcohol	40	(0.6%)	43	(0.7%)	45	(0.7%)
Health	50	(0.7%)	39	(0.6%)	39	(0.6%)
Prostatic	43	(0.6%)	44	(0.7%)	43	(0.7%)
Clinical	46	(0.7%)	39	(0.6%)	38	(0.6%)

*Numbers in parentheses indicate the frequency with which the term is contained in PI abstracts of affiliate-managed research projects.

Summary for Question 6a

- Although academic affiliates manage extramural research funds from multiple sources, NIH funded two-thirds of all affiliate-managed grants in 2014, 2015 and 2016.
- The kinds of research supported by affiliate-managed grants span a wide range of health issues and diseases that affect the 9 million+ Veteran beneficiaries served by VA healthcare.
- There are more than 1800 keyword descriptions used by VA investigators to describe the subject matter of their research grants. Frequently listed research topics include cancer, injuries, diabetes, heart and kidney disease, alcohol dependence and brain function.

Q6b. How many of the research projects conducted at the university use a majority of Veterans as subjects?

RDIS does not contain a specific designation for projects that utilize Veterans as the majority of research subjects. Many projects, in fact, do not involve human subjects at all, such as research on animals, or studies that rely on existing administrative data such as medical records. However, grants entered in RDIS do include a designation for "human use" that identifies if human subjects are involved in a project. Moreover, PIs are also required to report the share of work conducted at VA for each project, including those coded as "human use". In order to address this research question, we categorized any project that was (a) coded as "human use" and (b) performed mostly or fully at VA (51% or more), as a project that used Veterans as the majority of subjects. Although we cannot confirm through RDIS that all projects in which both (a) and (b) are true actually use Veterans as the majority of subjects—we consider our approach the best available method to answer this research question, given data limitations.

Table 3-13 shows the distribution of all projects coded as human use, by year and by administrative entity (i.e., NPC vs. affiliate). The table indicates that NPCs administer the majority of VA investigators' research projects involving human research subjects. In 2014 for example, of the 2,711 projects involving human use, 1,950 (72%) were administered by the NPC. In both 2015 and 2016, approximately three-fourths of projects involving human subjects were managed by the NPC.

Table 3-13. Extramural grants coded as human use, by year and administrator

	2014	2015	2016
Administered by Affiliate	761 (28%)	670 (25%)	609 (24%)
Administered by NPC	1,950 (72%)	1,987 (75%)	1,894 (76%)
Total	**2,711 (100%)**	**2,657 (100%)**	**2,503 (100%)**

Table 3-14 displays, by year and administrative entity, the subset of VA investigator projects that (a) involved human subjects, and (b) were performed mostly or completely at VA. Based on the assumptions described earlier, these projects most likely involve Veterans as the majority of subjects.

Table 3-14. VA extramural projects involving Veterans as the majority of subjects*

	2014	2015	2016
Administered by Affiliate	384 (21%)	314 (18%)	307 (18%)
Administered by NPC	1,456 (79%)	1,421 (82%)	1,355 (82%)
Total	**1,840**	**1,735**	**1,662**

*RDIS contains no direct indicator of which projects use a majority of Veterans as subjects. As a proxy measure, we use grants coded as "human use" in which more than 51 percent of the work is conducted at VA.

The table shows that PIs conducted an average of 1,746 projects per year between 2014 and 2016 that involved Veterans as the majority of subjects, and that NPCs administered the large majority of these projects. In 2014 for example, NPCs administered 79 percent of the 1,840 projects involving Veterans as the majority of subjects, and they administered a slightly higher share (82%) of such projects during 2015 and 2016.

In 2014, academic affiliates administered 384 grants that involved Veterans as the majority of subjects, or 25.5 percent of all affiliate-managed grants. (The total number of affiliate-managed grants was shown earlier in Table 3-11). In 2015, the affiliates administered 314 grants that used Veterans as a majority of subjects, which was 22.7 percent of all affiliate managed grants. In 2016, affiliates managed 307 grants that used a majority of Veterans as subjects, or 22.7 percent of all affiliate managed grants.

Slightly less than one-fourth of research projects managed by academic affiliates between 2014-2016 used a majority of Veterans as subjects.

Summary for Question 6b

- On average, over the three-year period from 2014 through 2016, 23.6 percent of research projects managed by academic affiliates used a majority of Veterans as subjects.

Q8. What are academic affiliates' policies for the administration of a federal grant involving one of its employees when the research is performed at the VA?

- **Q8a. Do the academic affiliates comply with all VA regulations and policies?**
- **Q8b. Are they held to the same standards as the VA NPCs?**
- **Q8c. Do these policies conflict with each other?**
- **Q8d. Does it cause a conflict for the employee?**
- **Q8e. Who manages the conflict?**

Questions 8(a) through 8(e) focus on potential differences between research policies in place at VAMCs around the nation and the academic affiliates with which VA researchers collaborate. As noted, the large majority of VA investigators who collaborate with academic affiliates have dual appointments with both organizations, and as such, there is the possibility that VA PIs may confront different or even conflicting policies and regulations pertaining to research conducted at both locations. Because ACOSs for Research are the main liaisons between the VAMCs and the affiliates and are in the best position to be familiar with both VA and affiliate research policies—and because many are or have been active VA PIs themselves—we posed this series of questions to all ACOSs interviewed for the study. Below we summarize their responses.

Most ACOSs reported that affiliate research policies do not conflict with those of VA.

Although there was general acknowledgment that the regulatory climate tends to be stricter at VA than at the affiliates, most ACOSs told us that, in their experience, research policies and practices at the affiliate and VA did not differ in meaningful ways, and that there was little to no conflict regarding research policies at their location. Interviewees who had this view told us that both the VAMC and the university are guided by well-established practices and methods that are federally and locally mandated and commonly accepted in the scientific community. These policies and methods cover issues such as the protection of human subjects, protection of animal welfare, standards and practices to ensure appropriate handling of hazardous materials (biosafety), and other topics:

> *"We know that [the affiliate is] enforcing the same human subjects [protection] rules. We know that there are institutional differences in regard to the type of HIPAA forms used...That kind of thing. But, I think generally, the same standards [are used] for*

[research with] animals, [and] the same standards [are used] for [research with] humans.
–ACOS for Research at VAMC in Group 3

"[Research policies and procedures] do not differ [between the affiliate and VA]. I have been very diligent in making sure that they do not….[Research standards and best practices] are exactly the same.
–ACOS for Research at VAMC in Group 2

"I think that basically the standards are very similar across institutions. And so from a scientific regulatory standpoint, the IRB – all of the IRBs are up to snuff, all the IACUCs are AAALAC accredited, so they all meet a high standard of performance within their domain."
–ACOS for Research at VAMC in Group 1

Interviewees told us that their affiliates, including PIs with dual appointments, comply with VA's regulations and policies when work is performed collaboratively. They explained that PIs, even if they have university appointments, must and do follow VA protocols and standards in order to conduct research at the VA or when it involves Veteran subjects:

"We're held to a higher standard than other folks are. We have to have the same rules and regulations as someone outside the VA does, plus we have the VA handbooks. VA is very process and protocol-driven. And my office makes sure that everybody, including the nonprofit corporation and the academic affiliates, comply with those policies."
–ACOS, for Research at VAMC in Group 1

Many interviewees who stated that VA and affiliate research policies are not in conflict also acknowledged that rules for conducting research at VA are often more stringent that those at the affiliate. Several noted that the VA may have different forms to be completed, and that VAMCs have an R&D Committee at each location that must approve each project in addition to IRB review. These interviewees did not consider such requirements as fundamental differences in research standards or practices, however. They viewed them instead as additional administrative steps instituted by VA to protect Veterans, and in most cases explained that the affiliate was supportive and accommodating of VA-specific practices:

"I don't think they conflict at all. I mean, it's certainly different. They have different policies. But as far as administering a grant and those sorts of things, I don't think they conflict… [the affiliate] is very responsive and supportive."
–ACOS for Research at VAMC in Group 3

In general, ACOSs did not believe dual appointed employees regularly experience conflicts created by different sets of policies. There was acknowledgement that difficulties do arise, such as when a PI

becomes disgruntled when they learn a VA rule is more stringent, but they stressed communication and education as the solutions for resolving such problems. Similarly, several interviewees stressed that active communication with their affiliate was beneficial in ensuring the affiliate and dual appointed PIs are aware of VA's research policies, practices and any unique requirements:

> *"Sometimes, there may be required VA items in the policies and procedures that are not required items on the university side. But, the way we handle those types of things is to work in concert with the affiliate to make sure…that we're compliant."*
> –ACOS for Research at VAMC in Group 3

> *"We [the VAMC] interact with them [the affiliate] and to solve problems where they're still rather small. So for example, at least once a year…the IRB main administrative officers at [the affiliate] and ours get together for about a two-hour session…It's very cordial…And they go over the new rules because it's always in flux… [They discuss] 'well, how's the university going to handle that?' [and] 'how's the VA going to handle that?' They kind of anticipate this thing."*
> –ACOS for Research at VAMC in Group 1

> *"When we manage [investigators] on the VA campus they have to follow the VA rules…An investigator can't tell me, 'Oh, I'm not following that rule because I am funded by the NIH'. [We explain that] 'You're on the VA campus, you follow all the VA rules, and [the affiliate rules].'… So you have to make sure you and all your staff have…updated training, you follow all data use agreements, compliance, everything."*
> –ACOS for Research, at VAMC in Group 1

> *"[An] investigator may come to me and say, 'Well, they allow this at [the affiliate].' But then when we pull up the rules at [the affiliate], then they'll realize that no, they don't allow this. It's just that they don't police it as much as they do at the VA."*
> –ACOS for Research at VAMC in Group 1

Many Affiliates work closely with VA to ensure compliance with VA standards to facilitate the research of dual appointed investigators.

We heard many examples in which affiliates were working with VA to ensure dual appointed researchers comply with VA policies and regulations when conducting collaborative research. Many ACOSs described a process in which, once the relevant affiliate committees and staff are made aware of VA policies and regulations applicable to collaborative research, affiliates abide by those policies and ensure they are followed:

> *"So any VA that uses an academic affiliate, either for their IRB and/or their Animal Care and Use Committee, then when we get our policy changes from ORD regarding VA research, then, of course, we have to work with our affiliate IRB human research personnel. We work with them to make sure that our policies are written into their*

overall policy... We work really well together."
–ACOS for Research at VAMC in Group 3

"It was really hard to ask all those [affiliate] committees to understand all the VA rules…[but] we worked with [the affiliate] and they were very gracious, and they made [an IRB that is] only for VA…they all learned the VA rules and regulations, and they do a great job, and we work with them. It's a partnership."
–ACOS for Research at VAMC in Group 1

At some locations where the affiliate and VA maintain a joint IRB, or where university maintains the IRB of record, ACOSs told us that potential conflicts are avoided in part by having VA personnel serve on the joint or university IRB when it reviews collaborative projects:

"We have the human studies administrators in my office embedded into the IRB to make sure that the IRB knows all the VA rules and approvals get done that are properly VA. [The affiliate said] 'Wow, that's a good idea,' because we want to be maximizing the ability to do research, and this would get rid of a barrier."
–ACOS for Research at VAMC in Group 1

Polices and standards regarding Information Security and Privacy were those most likely to be seen as different between the VA and the affiliate.

Slightly less than half of ACOSs told us that affiliate research policies and procedures did differ from those of their VA. Of those who expressed this view, about half said policies and procedures only differed sometimes, or in specific areas. The most common areas in which interviewees said policies and practices differed had to do with information security rules and data sharing. Many interviewees explained that VA's policies and rules regarding data security, which are intended to protect Veteran privacy and unauthorized access to VA data, are more rigorous than those at the affiliate:

"By and large, the VA is more rigorous in terms of how we look after the privacy of patients…And so we find that the affiliates are much more lax with regard to that. So if you're comparing the NPC with our affiliate, there are differences because the NPC is following these more rigorous VA rules."
–ACOS for Research at VAMC in Group 3

"Same rules apply, except the VA is more stringent in certain things."
–ACOS for Research at VAMC in Group 2

"You also have significant security issues within the VA that the university doesn't have for clinical activities."
–ACOS for Research at VAMC in Group 3

A few ACOSs explained that the VA's process and regulations regarding data security, particularly as they apply to information systems and data sharing between VA and university collaborators, create challenges for investigators and even pose a barrier to effective collaboration and research:

> *"And on the VA side, there are…increasing barriers due to regulatory issues for doing human research… particularly in regards to privacy and information security and so forth. I can give you many examples, but we've lost a number of on-call investigators in recent years just because of the difficulties in conducting some kinds of research."*
> –ACOS for Research at VAMC in Group 1

> *"The VA has additional regulation in regard to information security, and we have to go through an ISO [Information Security Officer] approval process, and [the ISO] has to approve everything. And we have a privacy officer that has to approve everything…in the university setting they don't have that requirement… It's just really difficult, and each VA struggles because we are at the mercy of the local information security officer, and that local person has either very little knowledge of research or a lot of knowledge."*
> –ACOS for Research at VAMC in Group 3

> *"The overlay that the VA has in terms of bureaucracy and regulations and policy…makes it a lot easier for [PIs] to go through the university. And we've had to invest a significant amount of effort in trying to make it easier – administratively and regulatory-wise – for our investigators to work within the VA constraints."*
> –ACOS for Research at VAMC in Group 3

Summary for Question 8

- ACOSs had mixed views on the question of whether VA research policies and procedures differ from those of the affiliate, but the majority said that policies were similar and were not in conflict. Both affiliate and VA policies integrate scientifically accepted standards and practices for research.
- Many interviewees noted that the regulatory environment of VA is more stringent than that of the university. For example, projects performed at VA or that use VA patients receive additional levels of administrative scrutiny— such as from the VA's R&D Committee—compared to non-VA studies conducted solely by the affiliate, and interviewees said VA approval tends to require completion of more paperwork.
- Although the administrative burden to perform work at VA may be greater, ACOSs do not generally interpret VA-unique administrative requirements as fundamental differences between research policy or practices at the affiliates and VA.
- ACOSs explained that both the NPC and the affiliate are required to abide by applicable VA regulations and policies when administering grants performed fully or in part at VA, and they are both required to comply with regulations stipulated by the funding agency (e.g., NIH).
- Interviewees told us that affiliates work in collaboration with the VA to maintain VA's standards and regulations when dual appointed VA staff are conducting collaborative projects with the affiliate. Many ACOS were complimentary of their affiliate's efforts to incorporate VA-specific procedures.
- Most ACOSs did not believe employees experience serious conflict due to different research policies between the VA and the affiliate. Several ACOSs explained that conflict is avoided by ensuring that the affiliate and PIs are aware of and comply with VA regulations applicable to collaborative research. VA representation on joint or affiliate-led IRBs is one way that VAMCs achieve this goal.
- A minority of interviewees said that research policies and procedures between the affiliate and the VA are different in some ways, with most noting that VA data security procedures and policies related to privacy/data sharing were much more stringent or burdensome compared with the affiliate. Some ACOSs cited examples in which they felt VA's regulations and procedures in this area posed a barrier to collaborative research.

Q9. How does the VA benefit when federal grants are administered by the local academic affiliate?

With only a few exceptions, all VAMCs with research activity have an affiliated academic institution, usually a medical school at a university. Most VAMCs are located near their affiliates—some are on adjacent campuses—and a few are joined by a sky bridge between buildings or a system of shuttles (the latter provided by the university).

After WWII, when the VA began to hire physicians with academic affiliations, the VA found it had to rely on its affiliate for research resources, including laboratories, equipment, technical staff, and administration, as VA hospitals were not suitably equipped for conducting research.[28] Since then, VHA's research resources have become much more extensive. Even so, many interviewees told us that dual appointed VA PIs continue to rely on resources and services at their affiliates to execute projects funded by extramural grants (NIH, predominantly) and intramural Merit Awards.

When asked how the VA benefits when the local academic affiliate administers federal grants, interviewees described how their academic affiliates provided resources and services to strengthen VA research. They explained that the federal grants they receive help pay for the resources and services used when the research is conducted at the academic affiliate. Below, we describe what interviewees believed were the most important resources and services they received from their academic affiliates. These include:

- Laboratory space and equipment;
- Access to core laboratories, animal facilities, "wet" laboratories, etc. on campus;
- Computing and library resources;
- Compliance infrastructure, to include the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee (IBC) of record;
- Scientific and intellectual community and continuing education;

[28]Veterans Health Administration, Office of Academic Affiliations. *The Report of the Blue Ribbon Panel on VA-Medical School Affiliations: Transforming an Historic Partnership for the 21st Century*, p. 92.

- Assistance with attracting, recruiting, and retaining the best researchers; and
- Salary support for workweeks exceeding 40 hours.

Laboratories and Equipment Resources Available at Academic Affiliates

For VA researchers, an affiliated university provides important resources for research, including laboratories, computing facilities, and compliance infrastructure. Many affiliates provide dual appointed VA PIs with office and laboratory space so that some VA PIs have two laboratories: a laboratory at the VA and a laboratory at the affiliate. In some cases the PI's only laboratory is located at the affiliate, to avoid duplication of resources.

In addition to laboratory space, PIs have access to the university's specialized scientific equipment, as organized in core laboratories. A core laboratory brings together multi-million dollar state-of-the-art research equipment in one facility. Specialized workers run and maintain the equipment. A group of scientists working on independent projects may rely on the core to complete their projects. In interviews, ACOSs and EDs described the availability of core laboratories at the affiliate as crucial for conducting VA research funded by Merit Awards and other federal grants.

ACOSs mentioned animal facilities and "wet labs" as other important resources at the academic affiliate. A number of VAMCs do not have facilities for keeping animals that may be necessary to execute their projects. Therefore, PIs at these VAMCs rely on the animal facilities at the affiliate. Likewise, some VAMCs do not have wet labs (a laboratory constructed to conduct typical bench science experiments), so dual appointed VA PIs may use affiliates' wet labs when appropriate. For example, one ACOS who is also a dual appointed PI explained that she, and many of her VA colleagues who hold NIH grants requiring the use of wet laboratories, must conduct all of their NIH-sponsored research necessitating a wet lab at the affiliate. Her VAMC does not provide wet labs. In other cases, VA PIs told us that they have made use of affiliate labs when needing to handle hazardous materials VA labs did not have the necessary set ups to handle.

Furthermore, most, if not all, academic affiliates have more extensive libraries, more powerful computing facilities, and a greater range of analytic software than VAMCs. Some ACOSs said that the data sets used for their PIs' research are often so massive that they cannot run on VAMC computers. Instead, these PIs rely on computing facilities at the affiliate. ACOSs also noted that VA email has size limitations, making it impossible to pass around big data sets with colleagues, or even

submit journal articles. Sending and receiving foreign e-mails is also restricted at the VA for security reasons. Therefore, dual appointed VA PIs rely on their university email accounts for collaboration:

> *"[The medical school] allows us to have access to their computer network. We have a separate computer system…that allows us to use [medical school] email, which does not have size attachment limitations like VA email does. One could never be a scientist in the modern times with the big data sets we pass around with colleagues and do it on the [VA] system.... For example, all of the genome projects that are all being done, and the massive data sets that we're looking at just couldn't be done on a VA computer."*
> –ACOS for Research at VAMC in Group 2

Other resources that affiliates provide to the VA include small grants to VA PIs for research projects. Large university medical schools frequently have small pots of grant money that faculty may apply for to conduct exploratory research ("seed funding") or help them continue their line of research while they are in-between major research grants ("bridge funding").

Compliance Infrastructure at the Academic Affiliates

Affiliates' compliance infrastructure are resources monitoring the fulfillment of ethical and safety requirements in the execution of research. They include the Institutional Review Board (IRB) that ensures compliance with the ethical conduct of research with human subjects; the Institutional Animal Care and Use Committee (IACUC) monitoring the humane use of animals in research; and the Institutional Biosafety Committee (IBC), which assesses the safety to researchers and the surrounding community of laboratory procedures for handling biohazards. All federal and private institutions conducting research in the United States must comply with the ethical and safety guidelines these boards and committees surveil. Most institutions that conduct biomedical research, including medical schools, form these regulatory bodies and encourage or require researchers to serve on them to evaluate colleagues' compliance.

Research conducted at the VAMCs must meet or exceed the same ethical and safety standards as research conducted at other US institutions. VAMCs may rely on internal regulatory bodies (IRBs, IACUCs, and IBCs) to approve and monitor VA research, and VA PIs benefit from the compliance infrastructure of their medical school affiliates.

It is important to note that all research by dual appointed VA PIs that takes place at the affiliate are subject to the affiliate's compliance procedures, and therefore, receive approval from the affiliate's compliance committees. However, many VAMCs rely on their academic affiliates' compliance

infrastructure for *all* their research, including industry clinical trials and intramural research funded by Merit Awards. That is, if the affiliate serves as the VAMC's IRB of record, the VAMC will not have its own IRB committee. Under these arrangements, researchers appointed solely by the affiliate share the burden of staffing regulatory committees with dual appointed VA researchers.

In the absence of these shared committees, the VA would have to staff these committees fully with their own researchers. One ACOS explained the disadvantage of running regulatory committees in-house in the following way:

> *"If we don't get [compliance infrastructure] at the affiliate, I have to create my own committees, and who is going to staff those committees? [Referring to "Best Doctors" article with VAMC researchers named] These people. They don't want to staff those committees. They'll have to, and then, they don't get time to see patients."*
> –ACOS for Research at VAMC in Group 1

This ACOS argued that relying on the affiliate's compliance infrastructure frees physician-researchers to treat Veterans. An ACOS at another VAMC with a smaller research program than the ACOS above, explained:

> *"We use the academic affiliate's Institutional Biosafety Committee [IBC] because we don't have the expertise or numbers necessary to staff it. One of the problems is there's so many mandates for committees at the VA, and we have more committees and committee slots than we have people to staff them….And so we rely on some help from our academic affiliate."*
> –ACOS for Research at VAMC in Group 1

The Academic Affiliate Provides a Scientific Community for Collaboration and Further Education

ACOSs thought that the opportunity to participate in an intellectual community of scientists, and collaborate with other elite researchers at the affiliate was critical to producing high-quality research. For example, an ACOS explained, "[The university] is such an academic powerhouse, both in science and they have great clinicians and that kind of thing. You go to conferences, you talk to colleagues—it's a really great intellectual environment." Another ACOS said:

> *"We benefit from the larger scientific community at the affiliate. As an example, our basic science operation here is somewhat small. It's growing again, but it's important to have a community of basic scientists to bounce things off of. We're lacking that now, so I think the affiliates really can fill the gap. We would look to our colleagues at the affiliate for collaboration if we're putting together something where we need a particular intellectual*

contribution."
–ACOS for Research at VAMC in Group 1

Affiliates also contribute to the continuing education of PIs:

> *"On an intellectual basis, again, the diversity of research seminars that are going on an hourly basis that are close by…a lot of our staff here take advantage and go over there [to the affiliate] to participate in educational seminars as well as other opportunities at the university."*
> –ACOS for Research at VAMC in Group 1

Academic Affiliates Attract and Recruit Top Scientists and Clinicians

The academic affiliate, in the words of one ACOS, "Can make you a professor. It can promote you on the academic side." Many ACOSs explained that elite researchers would have no interest in a career at the VA without an academic rank at the affiliate: "It's very hard to try to recruit anybody to come to our VA unless it comes with an academic position along with it." Researchers need academic rank at a university medical school to compete for grants other than VA Merit Awards. For example, an ED explained that some career development awards require the applicant to have a university appointment. Without an appointment, the researcher was not eligible to apply for these research grants. Other interviewees suggested that the affiliates were much better known to grant application reviewers than the NPCs:

> *""We have had some PIs get a comment on their grant [application] that 'We don't know what NPC stands for.' They would never get a comment like that if it were the university."*
> – ACOS for Research, VAMC in Group 2

Affiliates provide resources for the recruitment and retention of top-tier scientists at the VA. These resources include funds for job candidates to visit the VAMC and affiliate campus for interviews, start-up funds, laboratory space and equipment, and salary. ACOSs described feeling "dependent on the university's recruitment of faculty to bring new investigators into the VA," as there frequently is little to no funding to recruit scientists at the NPC or the VA. Further, universities are able to provide salary, laboratory equipment, computer equipment, and research start-up funds, all of which are very attractive to researchers. An ED explained, "So they [academic affiliate] let the VA hire for the position, and they give them a support package, start-up package, which is something not available on the VA side."

Offering resources above what the VA can provide to candidates for employment at the VA is how VAMC research programs recruit and retain top talent. Many ACOSs and EDs explained that it would be difficult to recruit the best researchers without the resources provided by the affiliate. One ACOS discussed negotiations in process to recruit a well-known researcher to the VAMC and its affiliated medical school:

> *"We're in discussion now for joint recruitment with the Department of Medicine to recruit a nationally-known [name of discipline] researcher who's a PhD, and the university is putting up two million….They're going to pay 60 percent of [the individual's] salary, and this person has two, three million dollars of NIH research, and has VA funding. No way a researcher like that's going to be working at the VA if it weren't in partnership with the university. We don't have the kind of resources to recruit people like that…"*
> –ACOS for Research at VAMC in Group 1

Another interviewee explained how collaborative recruitment works:

> *"If the Department of Surgery has a talented recruit that they're trying to bring to the VAMC, the [affiliate's] Department of Surgery might be involved in the recruitment and contribute resources for laboratory support, or perhaps a clinical practice opportunity…or that sort of thing."*
> –ACOS for Research at VAMC in Group 2

Another ACOS explained, "When I hired a wonderful [researcher], 100 percent VA-paid person, [the academic affiliate] pitched in about three hundred thousand dollars of a package for her because they knew she was going to be a huge asset, and she has."

The ACOS quoted above, who discussed hiring a star researcher, explained that having top-tier research faculty enhances clinical care for Veterans:

> *"You cannot care for Veterans with that complexity of illness if you don't have a [top researcher in that discipline]. The woman I just told you about, [star researcher], just recruited a fabulous [specialized clinician]. Why did he come to do research with her and me at this place? If we don't have her—and you wouldn't have me either probably—he's not going to come. Who's going to provide all the services so that [our Veterans] can have a [complex procedure] and get all the care after?"*
> –ACOS for Research at VAMC in Group 1

This ACOS stated that without an academic affiliate, the VAMC cannot offer Veterans cutting-edge care. That is, a top researcher needs and expects an academic affiliation in order to remain at the top of their field. Without cutting-edge researchers, the VAMC cannot recruit excellent clinicians,

because they expect to participate as researchers in important projects. Without the best clinicians, Veterans will not get the best care. As such, these interviewees believe academic affiliation is necessary to deliver superior clinical services to Veterans.

The Affiliate Provides Salary to Support the NIH-Funded Research of Dual Appointed VA PIs

Dual appointed VA PIs whose grants are managed by the affiliate (or, in other cases, whose grants are managed by the NPC, and then subcontracted to the affiliate) receive salary support from their grant to compensate for the time they spend working on their NIH grants. NPCs may not directly reimburse federal employees for hours worked above a 40-hour workweek when NIH is the salary source. However, with the added responsibility of the NIH grant, a VA PI may work up to 60 hours per week. An ED explained,

> *"The affiliate can pay a full-time federal employee from an NIH grant because they have an MOU with NIH that says 'We recognize that fully VA employees, faculty, also with a university appointment have a typical workweek of 60 hours. 40 hours doing VA work and 20 hours doing university academic functions.' Therefore, the NIH allows the university to pay faculty a salary from an NIH grant in addition to their full-time salary. The NPC cannot do that."*
> –Executive Director of NPC in Group 1

While some affiliates will allow the NPC to subcontract to them the portion of the grant that goes towards PIs' salaries, others will not. When this type of subcontracting is not allowed, the affiliate is more likely to manage NIH grants as prime with the NPC as a subawardee.

Trainees Enrolled in the Academic Affiliates Staff VAMC Hospitals

An important resource the affiliate makes available to the VA are trainees. Trainees include medical students, graduate students, and postdoctoral MDs and PhDs who conduct research in the laboratories of dual appointed VA PIs, and clinical trainees who serve as interns and residents at the VA hospital delivering clinical care to Veterans. An ACOS explained that because of their affiliation with one of the best medical schools in the country, "top medical students and top residents" provide clinical care to Veterans at the VAMC. Another ACOS explained:

> *"VA pays for residency slots, and the [affiliated medical school] runs those residency programs. It's an opportunity for the VA to achieve high quality, hard-working young people to run its services. The VA depends upon—heavily upon—[affiliated medical*

school] to run its specialty clinical services. By special I mean internal medicine, surgery, neurology…"
–ACOS for Research at VAMC in Group 3

A few ACOSs surmised that continuing to care for Veterans at the VA hospitals would be impossible if the affiliate withdrew support. One explained, "If for any reason the relationship [between the VAMC and the university] deteriorated to the point that they said, 'We're not going to send our residents and our fellows over there anymore,' clinical care at this medical center would collapse."

Summary for Question 9

- **When asked how the VA benefits when the academic affiliate administers federal grants, most ACOSs (who are generally also dual appointed PIs) described how the affiliates' services and resources strengthen VA research.**
- **The services and resources they referred to included:**
  - **Laboratory space and equipment;**
  - **Access to core laboratories, animal facilities, "wet" laboratories, etc., on campus;**
  - **Computing and library resources;**
  - **Compliance infrastructure;**
  - **Scientific and intellectual community and continuing education;**
  - **Assistance with attracting, recruiting, and retaining the best researchers; and**
  - **Salary support for workweeks exceeding 40 hours.**

Q9a. How does the academic affiliate use the indirect fee to benefit VA?

The NIH describes indirect costs as "infrastructure costs required to conduct research." Indirect costs on NIH grants are broken into two types: facilities and administrative (F&A). Facilities costs include things such as maintaining and operating the laboratory building, library and computing resources, and other infrastructure needs that pertain to research. Administrative costs include grant administration, academic administration (president, provosts, VPs), personnel, payroll, financial management, purchasing, compliance infrastructure and others.

Direct costs on NIH grants are those the PI uses to conduct the research project for which she or he received the award. Direct costs are those that "can be identified specifically with a particular project" and include salaries, personnel, equipment, supplies, services, and patient care. NIH refers to them as "direct" because PIs and affiliates can list them as directly facilitating the specific project.[29]

A large majority of interviewees reported that the affiliate does not use the indirect fee on grants they administer to benefit the VA. About a third said that the affiliate uses the indirect fee to pay for resources at the affiliate that benefit the research endeavors of dual appointed VA PIs who run their projects at the affiliate. In the rest of this section, we discuss interviewees' views on this topic.

Among the more than half of interviewees who said the VA does not benefit from the indirect fee collected by the affiliate, most did not elaborate. Here is a typical sequence of interviewer-interviewee dialogue from the transcripts:

Interviewer: *When one of the affiliates administers one of the PI's grants, how does the affiliate use the indirect fee to benefit VA, if at all?*

ACOS: *Not at all.*

[29]Information on indirect and direct costs cites Rockey, Sally J. (2015) "Indirect Costs 101: How NIH Supports Research Infrastructure for Extramural Research," YouTube video at url: https://www.youtube.com/watch?v=1XvVibv2opQ, accessed August 30, 2018.

Several interviewees elaborated that the VA does not get any direct benefit from the indirect costs collected by the affiliate when administering dual appointed VA PIs' NIH grants, and described it as problematic:

> *"We really need funds to…support our infrastructure here. If the grant is administered by the university, we don't get anything. We tried to do this in terms of, well, space allocation. If the dual appointee had a Merit Review Award and an NIH R01, we would say, "Okay, let's say that 50 percent of that investigator's space here at the VA would be used for the NIH R01 award, and therefore, we should be getting at least part of the overhead that comes to you [affiliated university] from the NIH award."*
> –ACOS for Research at VAMC in Group 1

An ED at an NPC affiliated with a different VAMC in Group 1 likewise replied that indirect fees received by the affiliate do not benefit the VA's mission, and he contrasted this with how the NPC uses indirect fees to support the VA:

> *"…when [grants are] administered [at the affiliate], those indirects don't support the mission of VA research….All my indirect [dollars] support VA research. I fund two and a half people in that office over there….We do a small grant program where we use our indirects to fund small grants up to 25 thousand dollars…just recently, there was a [clinician/researcher] that wanted to come over here…and got a startup package at [the affiliate]…So we all met and the board discussed it, and we basically matched the startup package….That not only impacts research; that impacts patient care. So it goes to show that we're not here only for the research, but we now have a [clinician/researcher] on staff that was desperately needed…. the more indirects we have, the better we can actually give back to VA."*
> –Executive Director of NPC in Group 1

Another ED described the difficulty their NPC had with negotiating with the affiliate to share indirect costs over a period of years with no success:

> *"We negotiated with the university for probably two or three years as to how the VA and the Foundation should get its share of indirects for NIH grants where the work is being done on our campus…. They kept proposing things that were just not doable…in terms of sharing indirects".*
> –Executive Director of NPC in Group 1

A few ACOSs said that the VA does not benefit from the affiliates' indirect fees, but explained that, legally, the affiliate cannot directly benefit VA with indirect fees from NIH research. For example, an interviewee who worked closely with his affiliate's Sponsored Research department, explained that indirect fees on NIH grants cover two types of costs—facilities and administration—depending on what is negotiated with the federal government. He believed that to spend these funds in ways other than specified by the federal government was a violation of federal rules:

> *"I learned so much about indirect costs, which are now called F&A—facilities and administrative costs….You can only spend F&A costs according to the regulations…. Some smaller VAs who don't have this experience working with the academic affiliate think, 'If I could get federal grants into my foundation, I'm going to have all these indirect costs left at the end of the year that I can use for travel and recruiting….' Well, in fact, that is not true."*
> –ACOS for Research at VAMC in Group 2

Other ACOSs who said that indirect costs do not benefit the VA sometimes gave the interviewer detailed explanations about how indirect costs on NIH grants are calculated and spent at the affiliate. The following ACOS at a VAMC in Group 3 explained that the affiliate may not collect facilities costs for that portion of the NIH grant that the dual appointed VA PI conducts at the VA:

> Interviewer: *Does the affiliate use any of that [NIH] indirect fee to benefit VA?*
>
> ACOS: *No.*
>
> Interviewer: *Okay. Do you think that your VA…*
>
> ACOS: *Yeah, they're indirect. [If the work is done at the VA] they can't charge the grant the full F&A costs. It has to be proportional to what they're doing in terms of supporting the grant because we are also [supporting the grant] through the VERA allocation….I just wanted to make that clear: they're not charging the whole F&A to NIH if the research is being conducted in VA labs and it's VA research.*

According to this ACOS, the affiliate may only charge the NIH for indirect costs associated with supporting the affiliate's facilities (the "F" of F&A) for that portion of the work that takes place at the affiliate. They may not charge facilities fees for work taking place at the VA.

NPCs may only receive the administrative portion (the "A" of F&A) of NIH indirects, since to receive facilities fees from NIH would constitute billing the federal government twice for the same costs. Our interviewees explained that the NPC may not charge NIH for facilities costs for research

conducted at the VA, since the VA receives allocations for facilities through the Veterans Equitable Research Allocation (VERA).

For example, our interviewer had the following exchange with an ACOS at a VAMC in Policy Group 1:

> ACOS: *DHHS [the Department of Health and Human Services] has a policy that, in effect, prohibits the payment of F&A costs to federal institutions that include the VA.*
>
> Interviewer: *And so…where does the indirect fee for your portion come from?*
>
> ACOS: *That comes back to us via the VA's research VERA location. That's determined by our submission every year of a report on annual expenditures from grants we submit… We will include that activity, the NIH grant, even though it's being administered by the affiliate if a lot of the work, or some of the work, is being done at the VA.*

About a third of respondents said the VA does benefit from the indirect fee the affiliate receives on behalf of a grant awarded to a dual appointed VA PI. Almost all of those who responded that the VA does benefit, referred to a research resource described in the first part of this question. Those resources included grant administration, laboratories and equipment, computing facilities, library collections, compliance infrastructure, and scientific community and intellectual life. A typical answer in this category was the following: "So the affiliate, across the board, is providing computer connectivity, library services, all of their educational services, through the—they provide them to all their academics, all their faculty." An ACOS explained:

> *I think in my experience it's maybe more of an indirect help. Again the aforementioned environment, or the intellectual environment. The indirect help [is] in terms of the IRB as well as the biosafety program, and then even a couple of things I told you about in terms of having the shuttle bus.*
> –ACOS for Research at VAMC in Group 1

Another ACOS noted:

> *"Well, they provide certain services for grants administration. They sometimes provide space. We've talked about the cores [core laboratories]—which is a real positive—and some of the other activities that we don't have to duplicate. We do have, I think, a sharing arrangement with the IRB…if we had to set up our own IRB it would be substantially more expensive."*
> –ACOS for Research at VAMC in Group 2

Summary for Question 9a

- **The majority of interviewees reported that the affiliate does not use the indirect fee to benefit the VA.**
- **A third of interviewees explained that the affiliate uses the indirect fee to pay for resources at the university, which benefit the research endeavors of VA investigators who perform part of their research at the affiliate.**

Q10. What support does the university and the NPC provide to VA investigators submitting Federal grants?

VA Associate Chiefs of Staff and NPC Executive Directors were asked how their designated NPC benefits the VA and what types of services are offered to VA PIs. The overwhelming majority of respondents provided very positive responses regarding the contributions of the NPCs in their sites and most supplied lengthy lists of benefits. The discussion below focuses on NPC benefits most frequently mentioned by respondents. The benefits mentioned by respondents in order of frequency (but not necessarily of importance) are:

- The ability to hire research support staff with ease and to encourage the recruitment of high-caliber PIs;
- The facilitation of research at the VA utilizing non-VA funds;
- The ability to make purchases of equipment, materials, and space as needed for VA research;
- Support of the VA's educational mission through the award of travel funds and the organization of research events, conferences, specialist and speaker visits, and trainings for staff and PIs;
- The improvement of Veterans' health and healthcare provision through increased opportunities for participation in clinical trials;
- More personal and expeditious customer service focused on VA PI needs;
- Low indirect fees to support industry clinical trials and foundation grants;
- Pre and post-award grant administration services; and
- Ability to work with a grant administration staff that has a close alignment with the VA's mission.

We describe each of these benefits in greater detail below.

Ease of Hiring Research Staff

The most commonly mentioned service provided by the NPCs was the ability to hire (and lay off) research support staff and specialists needed for VA research in a quick timeframe; much faster and with fewer administrative hurdles than if the employee had to be hired by the VA itself.

Respondents mentioned also that the NPCs provided human resource services and payments for staff. Some NPCs employ dozens of staff at any given time. Research coordinators are most frequently needed but some NPCs also hire IRB specialists, informatics and IT staff, and many other specialists.

> *"I think our [NPC] is employing somewhere between 20 and 25 people right now. So they do their own HR for those people…that's one of the main functions … there may be nothing worse at this point than VA HR. To get … your run of the mill just bench laboratory technician, could take three to five months doing it through the VA. And through the nonprofit, we could probably get somebody on board in two weeks."*
> –ACOS for Research at VAMC in Group 2

> *"Now on grant timelines, if you have to wait 9 months, 12 months to bring somebody aboard, then you're not going to be realistic dealing with research. Non-profits …maintain a flexible pool of coordinators who can kind of move from study to study and have their efforts in different studies reapportioned as needed."*
> –ACOS for Research at VAMC in Group 3

> *"[Through the NPCs]… there's a lot more choice in the candidates because we're not restricted by the very restrictive VA hiring mechanism, and the hiring can be done quickly to keep the project on time. If the project has any downsizing, we can downsize the staffing very quickly."*
> –ACOS for Research at VAMC in Group 3

Recruiting Scientists

In addition to the hiring of research support staff, respondents noted that some NPCs play a critical role in the recruitment of high caliber VA scientists. Some NPCs help provide seed funds that become part of recruitment packages and the existence of an NPC is pitched to prospective candidates as a means of taking advantage of non-VA research opportunities.

> *"…anytime that you have any opportunity for clinicians to conduct research, that allows …a recruitment tool because some very cutting-edge leading investigators who are clinicians also like to do research, and the opportunity to do research helped draw them into the VA medical center. That allows the medical center to have, I think, a higher quality of clinicians to conduct patient care at the VA."*
> –Executive Director of NPC in Group 1

> *"We pay for expenses for recruiting – and this is key to me. We have residual funds, and pay for recruitment for, say, doctors who have a research focus. With the university, we can recruit some top-notch physicians because we offer a great research mission. So …we contribute to the recruitment process for the VA medical center. No salary. But yeah. We could offer start-up packages for researchers."*
> –Executive Director of NPC in Group 2

"…if we're recruiting somebody, we can help contribute some to the startup package for that individual, and we also do provide them some discretionary administrative funds that are for their use that they don't have available through [the affiliate]."
–Executive Director of NPC in Group 1

Facilitating Research with Non-VA Money

A third of respondents commented on the importance of the NPC in attracting non-VA research funds. Many stated that without the NPC, there would barely be any worthwhile research conducted at their respective VA. Through the NPC, VA PIs are able to apply and obtain NIH, DoD, state, industry and private funding for studies to be conducted at the VA and with Veterans as subjects.

"…the VA can only handle VA money. And, if we depended on just the VA money to do research, then we wouldn't be doing a whole lot of research. So we absolutely need the nonprofit to be able to manage that funding so that we can have a viable research program."
–ACOS for Research at VAMC in Group 3

"These days it's very hard to simply run a laboratory, which I also do, with only VA ORD funds. So, to be able to have these other mechanisms to try to bring in other funds is – it's a necessity these days."
–ACOS for Research at VAMC in Group 2

"…well, right now our research program at this VA is so very, very small. The only studies going through right now are all administered through the nonprofit. There are no VA-funded studies…So if we weren't here, there probably right now wouldn't be a research program."
–ACOS for Research at VAMC in Group 3

Procurement of Equipment, Supplies and Space

Over a third of respondents noted the ease of making research related purchases through the NPC as opposed to the VA. The NPC can purchase computers, medical equipment and supplies, and facilitate research space rentals and laboratory repairs. Respondents noted the importance of this capability in encouraging and maintaining the VA's research agenda:

"Where you order supplies or whatever the issue is in terms of spending money that's related to a grant, the nonprofit corporations can do that much more efficiently, I think, than our local VA research office. There's just a lot less red tape."
–ACOS for Research at VAMC in Group 3

"So immediately we are the funding source for research service for capital equipment, for equipment and supplies …we have relatively no money, we raided our reserves to furnish our animal unit with just under $20,000 worth of contracting to replace floors and

otherwise remedy a repair situation."
–ACOS for Research at VAMC in Group 3

Promoting the VAs Education Mission: Conferences, Travel, Research Events, Junior Researcher Support, Mentorship

One of the most frequently mentioned benefits of NPCs is their ability to promote the VA's educational mission, encourage the continuing education of PIs and providing basic skills to young scientists. Respondents pointed to several avenues used by NPCs to enhance education, including travel awards, the planning and organizing of research events and conferences, and various group and individual trainings.

"…We support awareness-related and education programming across the different services. So for example, the mental health summit which is a Secretary-issued mandate that every VA hospital conduct a mental health summit…we draw more than 150 clinicians who come in."
–Executive Director of NPC in Group 3

"The [NPC] also can help us in training. If someone needs to establish a new skill, or a transgenic animal, or something like that, they help research move forward. And I think if we did not have the nonprofit, it would severely hamper what we're trying to do and where we're trying to go in research."
–ACOS for Research at VAMC in Group 2

"…over the last three or four years, we've tried to do a really significant research week here. And the NPC supports that through soliciting door prizes and providing some significant refreshments…I think if it weren't for the NPC doing those things, we probably wouldn't have anybody coming to those. And right now, every day we have 60 to 80 people at them every day over the noon hour."
–ACOS for Research at VAMC in Group 2

A few respondents mentioned that the award of small research grants, whether industry or seed funding, is fundamental to giving young investigators the opportunity to obtain valuable experience and kick-start their research agenda:

[The NPC has] given some of our junior clinicians an opportunity to learn how to do clinical trial research that they wouldn't have had if it wasn't for the NPC … With the clinical trials…they're local and they're smaller. Really, the scientists in those cases aren't really scientists, they're really kind of like following a recipe. But they learn some basics of research, so it's beginning science."
–ACOS for Research at VAMC in Group 2

"Our particular NPC … has benefited the VA by awarding small research grants to investigators that are early in their career with the idea to kind of kick start their research career. So that's sort of one tangible way that the NPC has benefited the VA. It kind of is supporting investigators which, as you probably are aware, are in many cases also the clinicians that see the Veterans here in the various VAs."
–ACOS for Research at VAMC in Group 3

Research events provide investigators the opportunity to network with other researchers and provide opportunities for mentorship and the exchange of ideas:

"The [NPCs] are able to do some things for investigators to offer incentives, as in using some of the residual funds to allow them to attend some conferences or do some things that are certainly a reward, in some respects, but also giving the investigators opportunities to network with other people who are doing similar work."
–ACOS for Research at VAMC in Group 2

"I think that our non-profit also serves as an important source of mentorship for clinical coordinators, for example, who are a participant to studies sponsored by the VA Cooperative Studies Program…There's kind of a pool of clinical coordinators there and they're obviously friends and colleagues, and they can mentor each other."
–ACOS for Research at VAMC in Group 3

Better Health for Veterans Through Access to Cutting Edge Medicines and Treatment

Over a third of interviewees emphasized in their responses the positive impact of the existence of NPCs on Veteran healthcare and health. NPCs administer industry trials of various pharmaceuticals, treatments, prosthetics and other health services, thus allowing Veterans access to cutting-edge treatments that have not yet received FDA approval and are thus not widely accessible. Respondents asserted that such access would not be possible without the NPCs:

"It opens up many more opportunities for our patients to be involved in some of these unique studies. So especially with the pharmaceutical company studies. We were very successful here with our Hep C studies, and a lot of the patients received drugs that normally would not have been given to them."
–Executive Director of NPC in Group 2

"I think outright if we weren't here then none of those clinical trials would be going. And thereby, none of the Veterans would be participating in any of these different studies. And these are important studies related to prostate cancer, diabetes, COPD, and asthma, all kinds of cardiology--related to devices, and therapeutics, and drug therapies for congested heart failure and such. So we're tallying hundreds of Veterans every year, participating in the clinical trials that we're managing."
–Executive Director of NPC in Group 3

"[Veterans] are the receiving end of that research and education. For example, we are bringing oncology trials here that did not exist before. So we have a lot of Veterans that are not receiving or not benefiting from oncology medications that could add months or longer to their lives or better quality of life. Without us being here and us bringing in that research, they wouldn't have it …Medical devices, medical procedures, best practices, pharmaceutical, that's what we're providing to them."
–ACOS for Research at VAMC in Group 3

In addition, Veterans benefit from the support of clinical trial staff who provide services that can enhance the care provided at the VAMC. A few respondents described the impact of these additional caregivers:

"…the NPC provides unbelievable opportunity for Veterans to participate in industry-sponsored studies that advances the clinical science but it also gives Veterans the opportunity to benefit from the TLC that participants always get in these studies…participants to a clinical trial benefit from that clinical trial whether they get the active treatment or not. Because they're being seen at very short intervals by caring clinical coordinators who are not just doing trial business but also giving moral support and helping these people, being kind of them, helping them through this illness that they have, or if they're being treated."
–ACOS for Research at VAMC in Group 3

"So what also happens, that people don't realize, is through these industry trials is often, as part of the trial, the industry will pay for a nurse, or a PA, or somebody who is the liaison to the patient. So the patient has this really great care team that is over and above their VA care team… You want your patients to have the best medicines for free. And then extra staff to help care for the patients. So, there are a lot of advantages."
–ACOS for Research at VAMC in Group 2

Personalized Customer Service

At least a third of respondents mentioned the nimble, expedient and efficient grant administration process of the NPCs. These respondents compared the NPCs favorably to their respective academic affiliates, which are typically larger bureaucracies, involving many staff members, procedures, and longer wait periods.

"…our NPC is a relatively small organization compared to our university, and so the university has very strict guidelines. You have to have your budget routed three or four weeks before the grant goes in, etc. I think the NPCs can be much more nimble and can put together some of that stuff on a much quicker timetable than the universities, so I always tell investigators, 'If you think you've missed your window to apply, sometimes you can get it done quite quickly with the NPC.'"
–ACOS for Research at VAMC in Group 3

"Really it's what I consider the best function is it's flexibility, the fact that you're not dealing with a behemoth administration, like you would on the other side with the university. It's generally – because it's a much smaller shop – then it's much more nimble and easier to deal with."
–ACOS for Research at VAMC in Group 2

Lower Indirect Fees for Industry Clinical Trials and Foundation Grants

Private foundations, commercial firms, and some other federal agencies outside of NIH that provide funding for the conduct of clinical trials generally expect the awardee to include their indirect costs as part of their application to receive the award and conduct the research. This is in contrast to NIH indirect costs, which are calculated as a percentage of the award and provided to the awardee in addition to the direct costs.

Since NPCs cannot claim facilities fees as part of their indirect costs[30] (see discussion under Question 9a), their overall overhead is lower than that of most academic affiliates, which require both facilities and administrative (F&A) fees. This means that VA PIs who use the NPC to manage their private foundation grants, industry clinical trials, and sometimes other federal (i.e., non-NIH) grants can devote a larger share of the award directly to their research activities. For example, an ACOS explained:

Over here [at the NPC], we don't charge for the facility portion because that's government already. And so we charge 26%, it's 25%, actually, indirect. And so, in DoD grants, that comes off the top. With NIH grants, they're separate from the-- there's that part of the indirect cost and not the direct cost. With the DoD, you get a sum of money. You get, say, $1 million. Well, those indirects come off the top of that. So if that would have been run through the university, they'd have been grabbing 52%, but here, we took 25.
–ACOS for Research at VAMC in Group 2

Another ACOS said:

[For] some foundation grants—where there's just a fixed amount to be allocated—non-federal grants, the indirect cost rate is generally lower so that a greater percentage of the funds will be able to go the investigator, not just used to support administrative costs.
–ACOS for Research VAMC in Group 1

[30]Facilities fees at VA are paid by the Veterans Equitable Resource Allocation (VERA).

An ED described how the PIs are happier when they are able to access more of their research money from an industry or private foundation grant:

> *"Our indirect cost is about half of what the university's is and some PIs are much happier with that. Because we don't have a facility overhead cost but the university does."*
> –Executive Director of NPC in Group 1

VERA Allocation is Higher When a Grant is Administered by the NPC

An additional financial benefit to the VA mentioned by many respondents is the accrual of VERA dollars every time the NPC administers a grant:

> *"So it benefits the research department by bringing in research dollars and doing VA-relevant research and supporting our Veterans…We get benefit, or at least the hospital gets benefit, because those dollars are counted toward our VERA allocation, and so the hospital gets more money the more money we spend over here."*
> –ACOS for Research at VAMC in Group 3

> *"Well, the VA definitely benefits because again, we can administer all that extramural funded research. And, again, that contributes toward the overall VA's VERA dollars that they get back in return. And here, at our site, we're probably about 50-50, the split between what's administered at the not-for-profit versus the VA side. So it's a big contribution to the VA total."*
> –Executive Director of NPC in Group 3

Pre-Award and Post-Award Grant Administration

A quarter of respondents described the pre- and post-award administrative services provided by the NPCs. NPC staff typically help write the administrative portions of a grant, prepare budgets, negotiate contracts, help with IRB packages, monitor projects and staff, among many other tasks.

> *"[One way] the nonprofit really helps us is that they have a very strong grant preparation service. So when an investigator prepares a grant for submission, the nonprofit has individuals who can help them put that grant together…they help to do a lot of that busy part of the application, and that frees up the investigator to really focus on the science."*
> –ACOS for Research at VAMC in Group 3

> *"Well, we offer the whole range of services that would go with any awards. I mean, we handle all the financials. We handle paying the employees on the study. We handle all the regulatory end of it, all the documents that have to be submitted –I'm kind of speaking of federal here, in particular, because they have a lot more demand –but we handle everything it takes to get the study going. So we're the awardees so we handle the interaction with the awarding agency."*
> –Executive Director of NPC in Group 2

Alignment with VA's Mission and Understanding of VA Rules

A few respondents pointed out that an advantage of the NPCs compared to the academic affiliates is their alignment with the VA mission and understanding of VA rules and regulations:

> *"…the NPCs … are a state incorporated non-profit, must adhere to all VA rules and regulations, and in particular, obviously any project that they manage has to be by definition VA research. So given that, they're probably in a little bit better position to be aware of VA rules and regulations, to be able to advise principal investigators and/or their staff on VA rules and regulations than the academic affiliates typically would."*
> –ACOS for Research at VAMC in Group 3

> *"The nonprofit only has one mission, and that is to support the mission of research at the VA. It can't be used to subsidize a university building program. It can't be used to offset all kinds of general costs in other parts of an institution…And as a result, it has much more local accountability and responsiveness than if we were simply another group in line at the university."*
> –ACOS for Research at VAMC in Group 2

> *"The NPC benefits the VA, and the Veteran in general, by supporting Veterans. Why? Because we're not taking any study who will not benefit the Veteran…Any study or any research or any education activity must benefit the Veteran, and this is the sort of thing we think about when approving any project or any education activity."*
> –Executive Director of NPC in Group 1

Summary for Question 10

(We discuss the support that the university provides to VA investigators in Question 9 above.)

- **EDs and ACOS reported that NPCs further the aims of research to improve Veterans' health by**
  - **Quickly hiring research support staff (research assistants, project managers, etc.) to serve on dual-appointed VA PIs' extramural projects;**
  - **Purchasing equipment and materials for extramural VA research;**
  - **Supporting VA's education mission with funds for travel to scientific meetings;**
  - **Organizing research events;**
  - **Increasing opportunities for Veterans to participate in clinical trials; and**
  - **Providing pre- and post-award grant administration services with more personal attention and friendly customer service.**

Q11. Does the nonprofit corporation have an explicit education mission in its bylaws? YES or NO?

Of the 71 NPC Executive Directors who were asked this question, 93 percent (66 of 71) said their NPC's bylaws include education as part of their mission.[31] Four of the five NPCs that did not have an education mission historically have never had education as part of their organization. When asked, they did not know why there has never been such a mission. The remaining NPC's Executive Director stated, "I think there was, but we need to work in conjunction with the VA and if there's not an education person in place at the VA, then it's kind of a moot subject."

Summary for Question 11

- **Ninety-three percent of NPCs (66 of 71) have an explicit education mission in their bylaws.**

[31]Although interviews were conducted with 72 Executive Directors, in one case the ACOS for Research was acting in the ED role. For that interview, we used the ACOS interview guide, which does not contain Questions 11 and 12.

Q12. Does the nonprofit corporation have the Associate Chief of Staff for Education as a statutory board member?

Ninety-four percent of Executive Directors (67 of 71) reported that their NPC has an Associate Chief of Staff for Education as a statutory board member, including one location at which the position is currently vacant. Four of the five NPCs that do not have an education mission also do not have an Associate Chief of Staff for Education. The other NPC that does not have an education mission stated that they had an education staff member in place in the past, but do not currently have anyone in that position.

An Executive Director of one NPC has an ACOS of Education who historically has not been on the board. The remaining three NPCs that do not have such a board member explained that they have or have had someone performing an education role but do not use the ACOS title: one NPC has a Chief Education Officer on their board, one has an Education Training Supervisor, or Designated Learning Officer, and a third had a Designated Learning Officer in the past but the position is currently vacant.

Summary for Question 12

- **Ninety-four percent of NPCs contacted (67 of 71) have an Associate Chief of Staff for Education as a statutory board member.**

Q13. What percent of grants and contracts are explicitly for education activities?

In order to answer this question, we reviewed and analyzed reported expenditures on education contained in the NPC Annual Reports for the years 2014 through 2016. While the NPC Annual Reports do not describe specific education grants, they do provide the total reported expenditures related to education for that year, and well as providing overall expenditures related to research. We used these reported totals to estimate the percentage of all research and education expenditures accounted for by education grants and contracts.

Table 3-15 shows yearly NPC expenditures for major categories of expenses: administrative, research, fundraising and education. The table indicates that expenses for research are by far the largest category of expenditures for NPCs—representing between 84 and 85 percent of all expenses, depending on the year. By contrast, spending on education ranged from less than 1 percent of total spending in 2014 to slightly over 1 percent in both 2015 and 2016.

Table 3-15. Total reported annual expenditures for NPCs, by category and year

	2014 ($)	2015 ($)	2016 ($)
Administrative expenditures	37,474,421 (14%)	36,932,736 (14%)	38,918,389 (15%)
Research expenditures	228,870,159 (85%)	228,999,586 (85%)	225,794,651 (84%)
Fundraising expenditures	98,757 (<1%)	44,923 (<1%)	155,276 (<1%)
Education expenditures	1,635,618 (<1%)	3,526,891 (1%)	3,268,924 (1%)
Overall expenditures	**268,078,955**	**269,504,136**	**268,137,240**

Excluding administrative and fundraising expenses allows us to examine NPC spending on research and education alone. In 2014, education expenses represented about one-half of 1 percent of the $230.5 million expended by NPCs on research and education. The share of spending on education relative to research, while still relatively small, more than doubled during 2015. In 2015, education spending represented 1.5 percent of the $232.5 million spent by NPCs on both research and education. In 2016, education expenditures were 1.4 percent of the $229 million expended on both missions.

Appendix A

Study Instruments

Appendix A
Study Instruments

VETERANS AFFAIRS (VA) EXTRAMURAL FUNDING PROJECT NON-PROFIT CORPORATION (NPC) EXECUTIVE DIRECTOR (ED) SITE VISIT INTERVIEW GUIDE

Thank you for participating in this interview. My name is [NAME] and this is/are my colleague(s) [NAME(s)]. We work for Westat, a research organization based in Rockville, MD. The VA Office of Research and Development in Washington D.C. asked Westat to conduct an independent study of how extramural funds received by VA Principal Investigators (PIs) are managed. Today we would like to hear about your experiences managing extramural funds from federal and private sources at your NPC.

For this study, Westat interviewers will be speaking with the Executive Directors of all 83 NPCs across the country, with some in person and some on the phone. We will submit a report to the VA at the conclusion of the study that explains our findings regarding the current roles of NPCs and Academic Affiliates in obtaining and managing extramural funding obtained by VA PIs. The VA ORD will be sharing the results of our report with the House Committee on Veterans Affairs (HVAC). We will not identify you or quote you directly, but it may be possible for readers of the report to identify you as a participant because of your role at the NPC.

Westat and the VA are grateful for your time and willingness to speak with us. We want to let you know that since this is a research study, we would like you to speak freely and let us know if you cannot answer a question. Please bear with us as some of our questions may seem redundant or awkward. Some answers may seem obvious. If you find that some of the questions we ask do not address your concerns about the management of extramural funding, please feel free to explain what it is you think we need to know.

We have planned for this interview to last not more than [xx] minutes. Do you have any questions at this time? [ANSWER ALL QUESTIONS.]

Finally, with your permission, we would like to record this interview. The recording will help us recall exactly what was said when we go to summarize our findings. Recordings and notes will be stored on Westat's computers and will be available only to the Westat project team. We will destroy the recordings after the study is complete. Are you okay with us recording?

[IF PERMISSION IS GIVEN TO RECORD, ASK AGAIN IF THERE ARE ANY QUESTIONS. ANSWER ALL QUESTIONS.]

If there are no further questions or concerns, I'd like to start the recording now.

[TURN ON THE RECORDER] For the purposes of the recording, I am going to ask you once again if you are you willing to participate in the interview. Can you please confirm?

Are you willing to have the interview recorded?

Thank you very much, so now we begin.

1. NPC PERSONNEL AND ROLES

    a. Executive Director

        (i) Please describe your work as the Executive Director of the [NAME] NPC.

        (ii) How long have you been in this position?

    b. Other NPC staff

        (i) How many staff work at this NPC?

    c. Associate Chief of Staff of Education

        (i) Does your NPC have the Associate Chief of Staff of Education (DOE) as a statutory board member?

            [IF NO]: Why not?

2. EDUCATION MISSION BYLAWS

        (i) Does your NPC have an explicit education mission in its bylaws?

            [IF NO]: Why not?

3. POLICIES AND PRACTICES FOR THE ADMINISTRATION OF EXTRAMURAL FUNDS

a. Policy for determining the grant institution

(i) Who decides whether the NPC or the Academic Affiliate will administer a research grant? How is the decision made? Please explain the process.

(ii) Are there local policies or guidelines (such as an MOU) for deciding where to manage the grant (VA vs. Academic Affiliate)? If there are guidelines, what are they?

(iii) How does the policy or grant administration strategy differ depending on the funding source (federal, non-profit, or industry)?

(iv) Are there differences between the types of research that the NPC and the academic affiliate manage? [IF SO] What are they? [PROBE]: clinical trials, animal research, disciplinary differences, private versus federal? Other? Where are industry-sponsored trials administered?

b. Subaward/subcontract policies

(i) If the majority of the work (i.e., greater than 50%) is conducted at the VA, does the NPC administer the funding?

(ii) When the University administers a grant that is partly conducted at the VA, is the NPC subcontracted, or subawarded, the portion conducted at the VA? Explain why or why not.

c. PI preferences

(i) Do you think PIs in your VA prefer handling their grants through the affiliate or the NPC? Why do you think that?

(ii) Is there a difference between the grant administration policy you described above and practice? Is there a difference between how PIs ought to choose an administrative authority (AA vs. NPC) and how they actually choose?

[IF YES] What is the difference? Why do you think there is this difference? How do PIs choose?

4. NPC SERVICES AND BENEFITS

(i) Can you describe what services this NPC offers to the VA and VA PIs?

(ii) In your view, how does this NPC benefit the VA?

(iii) How does the NPC benefit Veterans?

5. NPC POTENTIAL

   (i) Do you think that your VA's NPC is being utilized to its fullest potential by the VA PIs? Please explain why or why not.

6. ACADEMIC AFFILIATE IDENTIFICATION

   (i) It's our understanding that PIs at this VA may have affiliations with [NAMES OF ACADEMIC INSTITUTIONS]. Is this correct? Did I leave out an institution?

7. COMPARING ACADEMIC AFFILIATE AND NON PROFIT CORPORATION SERVICES

   (i) Are there functions that the NPC can perform more effectively than the academic affiliate?

   (ii) What are some of the functions Academic Affiliates perform that NPCs do not?

8. MISALIGNMENT OF THE ACADEMIC AFFILIATE AND THE VA

   (i) Do **research policies and procedures differ** across the NPC and the affiliate?

   [IF YES]: How do they differ? Are they in conflict?

   (a) Does the PI and other researchers experience the conflict? How?

   (b) [IF RELEVANT] Who resolves the disagreement?

   (ii) Are VA and academic affiliate policies ever **in disagreement**?

   [IF YES]: Which policies? Why is that?

   [IF RELEVANT] How are differences managed? Who manages them?

   Can you give an example?

   (iii) Are **research standards/best practice** guidelines the same at the NPC and the Academic Affiliates?

   [IF NO]: How are they different? Can you give an example?

9. CLOSING

   (i) Is there **anything we haven't already spoken about** in regard to VA PIs' extramural grants and their management at NPCs and Academic Affiliates that you think would be important for me to know?

   Thank you for your time!

VETERANS AFFAIRS EXTRAMURAL FUNDING PROJECT VETERANS HEALTH ADMINISTRATION (VHA) ASSOCIATE CHIEF OF STAFF (ACOS) OF RESEARCH AND DEVELOPMENT (ORD) SITE VISIT INTERVIEW GUIDE

Thank you for participating in this interview. My name is [NAME] and this is/are my colleague(s) [NAME(s)]. We work for Westat, a research organization based in Rockville, MD. The VA Office of Research and Development in Washington D.C. has asked Westat to conduct an independent study of how extramural funds received by VA Principal Investigators (PIs) are managed. Today we would like to hear about your experiences managing extramural funds from federal and private sources at [NAME OF VA].

For this study, Westat interviewers will be speaking with VA ACOSs across the country, with some in person and some on the phone. We will submit a report to the VA at the conclusion of the study that explains our findings regarding the current roles of Nonprofit Research and Education Corporations (NPCs) and Academic Affiliates (AAs) in obtaining and managing extramural funding obtained by VA PIs. The VA ORD will be sharing the results of our report with the House Committee on Veterans Affairs (HVAC). We will not identify you or quote you directly, but it may be possible for readers of the report to identify you as a participant because of your role at the VA.

Westat and the VA are grateful for your time and willingness to speak with us. We want to let you know that since this is a research study, we would like you to speak freely and let us know if you cannot answer a question. Please bear with us as some of our questions may seem redundant or awkward. Some answers may seem obvious. If you find that some of the questions we ask do not address your concerns about the management of extramural funding, please feel free to explain what it is you think we need to know.

We have planned for this interview to last not more than [xx] minutes. Do you have any questions at this time? [ANSWER ALL QUESTIONS.]

Finally, with your permission, we would like to record this interview. The recording will help us recall exactly what was said when we go to summarize our findings. Recordings and notes will be stored on Westat's computers and will be available only to the Westat project team. We will destroy the recordings after the study is complete. Are you okay with us recording?

[IF PERMISSION IS GIVEN TO RECORD, ASK AGAIN IF THERE ARE ANY QUESTIONS. ANSWER ALL QUESTIONS.]

If there are no further questions or concerns, I'd like to start the recording now.

[TURN ON THE RECORDER] For the purposes of the recording, I am going to ask you once again if you are you willing to participate in the interview. Can you please confirm?

Are you willing to have the interview recorded?

Thank you very much, so now we begin.

1. ASSOCIATE CHIEF OF STAFF

    (i) Please describe your role, as ACOS, in working with PIs, the NPC, and your academic affiliate to manage extramural funding.

    (ii) How long have you been in this position?

2. POLICIES AND PRACTICES FOR THE ADMINISTRATION OF EXTRAMURAL FUNDS

    a. Policy for Determining the Grant Institution

        (i) Who decides whether the Academic Affiliate or the NPC will administer a research grant? How is the decision made? Please explain the process.

        (ii) Are there local policies or guidelines (such as an MOU) for deciding where to manage the grant (VA vs. Academic Affiliate)? If there are guidelines, what are they? How are decisions made for each grant?

        (iii) How does the policy or grant administration strategy differ depending on the funding source (federal, non-profit, or industry)?

        (iv) Are there differences among the types of research that the academic affiliate and NPC manage?[IF SO]: What are they? [PROBE]: clinical trials, animal research, disciplinary differences, private versus federal? Other? Where are industry-sponsored trials administered?

b. Subaward/subcontract policies

(i) If the majority of the work (i.e., greater than 50%) is conducted at the VA, does the NPC administer the funding?

(ii) When the University administers a grant that is partly conducted at the VA, is the NPC subcontracted, or subawarded, the portion conducted at the VA? Explain why or why not.

c. PI Preferences

(i) Do you think PIs in your VA prefer handling their grant through the affiliate or the NPC? Why do you think that?

(ii) Is there a difference between the grant administration policy you described above and practice? Is there a difference between how PIs ought to choose an administrative authority (AA vs. NPC) and how they actually choose?

(a) [IF YES] What is the difference? Why do you think there is this difference? How do PIs choose?

3. NPC SERVICES AND BENEFITS

In your opinion, how does your designated NPC benefit the VA?

[PROBE:] What services does your designated NPC offer to the VA and VA PIs?

4. NPC POTENTIAL

Do you think that your VA's NPC is being utilized to its fullest potential by the VA PIs?

Please explain why or why not.

5. ACADEMIC AFFILIATE IDENTIFICATION

It's our understanding that PIs at this VA may have affiliations with [NAMES OF ACADEMIC INSTITUTIONS]. Is this correct? Did I leave out an institution?

6. ACADEMIC AFFILIATE SERVICES AND BENEFITS

a. What services or benefits does the academic affiliate provide to the VA? [PROBE]:

(i) Institutional review Boards (IRB)

(ii) Institutional Animal Care and Use Committees (IACUC)

(iii) Institutional Biosafety Committee (IBC)

(iv) Core labs

(v) Pre-award management

(vi) Post-award management

(vii) Off-site research space

(viii) HR employee benefits

(ix) Documentation

(x) Accreditation

(xi) Help with recruitment and retention

(xii) Other?

[IF NOT ALREADY DISCUSSED]:

(i) What support does the academic affiliate provide to VA investigators when submitting federal grants and how does it compare to the support provided by the NPC?

(ii) How do academic affiliates contribute to the recruitment and retention of VA scientists?

b. Comparing academic affiliate and NPC services

(i) What are some functions that affiliates perform that NPCs do not?

(ii) Are there some functions that academic affiliates perform more effectively than NPCs? Please explain.

c. Are there areas where the NPC is in better position to manage PI grants?

d. Indirect Costs

(i) When the affiliate administers a VA PI's grant, how does it use the grant's indirect fees to benefit the VA (if at all)?

e. Research on veterans

(i) Do you think that your VA's relationship with the affiliate enhances opportunities for research on the veteran population and/or on veteran health?

(ii) In your experience, how often do studies conducted at the affiliates use veterans as subjects?

7. MISALIGNMENT OF THE ACADEMIC AFFILIATE AND THE VA

(i) Do **research policies and procedures differ** across the NPC and the affiliate?

[IF YES]: How do they differ? Are they in conflict?

(a) Does the PI and other researchers experience the conflict? How?

(b) [IF RELEVANT] Who resolves the disagreement?

(ii) Are VA and academic affiliate policies ever **in disagreement**?

[IF YES]: Which policies? Why is that?

[IF RELEVANT] How are differences managed? Who manages them?

Can you give an example?

(iii) Are **research standards/best practice** guidelines the same at the NPC and the Academic Affiliates?

[IF NO]: How are they different? Can you give an example?

8. CLOSING

(i) Is there anything we haven't already spoken about in regard to VA PIs' extramural grants and their management at NPCs and Academic Affiliates that you think would be important for me to know?

Thank you for your time!

VETERANS AFFAIRS (VA) EXTRAMURAL FUNDING PROJECT DEAN OF RESEARCH [OR OTHER RELEVANT STAFF] SITE VISIT INTERVIEW GUIDE

Thank you for participating in this interview. My name is [NAME] and this is/are my colleague(s) [NAME(s)]. We work for Westat, a research organization based in Rockville, MD. The VA Office of Research and Development in Washington D.C. has asked Westat to conduct an independent study of how extramural funds received by VA Principal Investigators (PIs) are managed. Today we would like to hear about the experiences of your academic institution accepting and managing grants for PIs who are dually-appointed at your institution and at the VA.

For this study, Westat interviewers will be speaking with grant administrators at the VA, the Non-Profit Corporations (NPC) and their Academic Affiliates across the country, with some in person and some on the phone. We will submit a report to the VA at the conclusion of the study that explains our findings regarding the current roles of Nonprofit Research and Education Corporations (NPCs) and Academic Affiliates (AAs) in managing extramural funding obtained by VA PIs. The VA ORD will be sharing the results of our report with the House Committee on Veterans Affairs (HVAC). We will not identify you or quote you directly, but it may be possible for readers of the report to identify you as a participant because of your role at [NAME OF AFFILIATE].

Westat and the VA are grateful for your time and willingness to speak with us. We want to let you know that since this is a research study, we would like you to speak freely and let us know if you cannot answer a question. Please bear with us as some of our questions may seem redundant or awkward. Some answers may seem obvious. If you find that some of the questions we ask do not address your concerns about the management of extramural funding, please feel free to explain what it is you think we need to know.

We have planned for this interview to last not more than [xx] minutes. Do you have any questions at this time? [ANSWER ALL QUESTIONS.]

Finally, with your permission, we would like to record this interview. The recording will help us recall exactly what was said when we go to summarize our findings. Recordings and notes will be stored on Westat's computers and will be available only to the Westat project team. We will destroy the recordings after the study is complete. Are you okay with us recording?

[IF PERMISSION IS GIVEN TO RECORD, ASK AGAIN IF THERE ARE ANY QUESTIONS. ANSWER ALL QUESTIONS.]

If there are no further questions or concerns, I'd like to start the recording now.

[TURN ON THE RECORDER] For the purposes of the recording, I am going to ask you once again if you are you willing to participate in the interview. Can you please confirm?

Are you willing to have the interview recorded? Thank you very much, so now we begin.

1. ROLE OF INTERVIEWEE

    (i) Please describe your current role.

    (ii) Please describe your role in the administration of grants for PIs dually-appointed at your institution and the VA.

2. POLICIES AND PRACTICES FOR THE ADMINISTRATION OF VA PROJECTS

    a. Policy for determining the grant's administering institution

        (i) Who decides whether your institution or the NPC will administer a dually appointed PIs research grant? How is the decision made? Please explain the process.

        (ii) Are there local policies or guidelines (such as an MOU) for deciding where to manage the grant (NPC vs. Academic Affiliate)? If there are guidelines, what are they? How are decisions made for each grant?

    b. Types of dually appointed PI research projects

        (i) Are there specific types of dually appointed PI grants that [NAME OF ACADEMIC AFFILIATE] are more likely than the NPC to administer?

        [IF YES]: Which ones? Are clinical trials, animal research, disciplinary differences, private versus federally funded projects handled differently? NIH?

        (ii) Are there specific types of dually appointed PI grants that the NPC is more likely than [NAME OF ACADEMIC AFFILIATE] to administer?

        [IF YES]: Which ones? Are clinical trials, animal research, disciplinary differences, private versus federal funded VA projects handled differently? NIH?

(iii) Does [NAME OF ACADEMIC AFFILIATE] administer industry-sponsored trials?

c. Subaward/subcontract policies

(i) When the University administers a grant that is partly conducted at the VA, is the NPC subcontracted, or subawarded, the portion conducted at the VA? Explain why or why not.

d. Academic affiliate preferences

(i) Under what circumstances do you prefer that your institution manage dually appointed PI grants instead of the Non-Profit Corporation (NPC)?

(ii) Under what circumstances do you prefer that the NPC manage dually appointed PI funds instead of [ACADEMIC AFFILIATE NAME]?

(iii) From your perspective, what is the difference between administering a dually appointed PI project at your institution and managing a portion of a dually appointed PI's grant that may come through the Non-Profit Corporation (NPC)?

[PROBE]: time spent administering, indirect costs, other

3. ACADEMIC AFFILIATE SERVICES AND BENEFITS

(i) When managing the projects of dually-appointed PIs, what services or benefits does your institution provide to the VA? [PROBE]:

(a) Institutional review Boards (IRB)

(b) Institutional Animal Care and Use Committees (IACUC)

(c) Institutional Biosafety Committee (IBC)

(d) Core labs

(e) Pre-award management

(f) Post-award management

(g) Off-site research space

(h) HR employee benefits

(i) Documentation

(j) Accreditation

(k) Help with recruitment and retention

(l) Other?

[IF NOT ALREADY DISCUSSED]

(i) What support does your institution provide to dually-appointed investigators when submitting federal grants?

(ii) How does your institution contribute to the recruitment and retention of VA scientists?

a. Comparing academic affiliate and NPC services

(i) What are some of the functions your University can perform that NPCs do not?

(ii) Are there some functions that your University can perform more effectively than the NPC? Please explain.

(iii) Are there areas where the NPC is in better position to manage PI grants?

b. Indirect costs

(i) When your University administers a dually appointed PI's grant, how does it use the grant's indirect fees to benefit the VA (if at all)?

c. Research on veterans

(i) Do you think that your University's relationship with the VA enhances opportunities for research on the veteran population and/or on veteran health?

(ii) In your experience, how often do studies conducted at [Name of AA] use veterans as subjects?

4. MISALIGNMENT OF THE ACADEMIC AFFILIATE AND THE VA

(i) Do **research policies and procedures differ** across your institution and the VA?

[IF YES]: How do they differ? Are they in conflict?

(a) Does the PI and other researchers experience the conflict? How?

(b) [IF RELEVANT] Who resolves the disagreement?

(ii) Are your policies ever **in disagreement with the VA's policies**?

[IF YES]: Which policies? Why is that?

[IF RELEVANT] How are differences managed? Who manages them?

Can you give an example?

(iii) Are **research standards/best practice** guidelines the same at your institution and the VA?

[IF NO]: How are they different? Can you give an example?

5. CLOSING

(i) Is there anything we haven't already spoken about in regard to VA research projects and their management that you think would be important for me to know?

Thank you for your time!

VETERANS AFFAIRS (VA) EXTRAMURAL FUNDING PROJECT PRINCIPAL INVESTIGATOR (PI) SITE VISIT INTERVIEW GUIDE

Thank you for participating in this interview. My name is [NAME] and this is/are my colleague(s) [NAME(s)]. We work for Westat, a research organization based in Rockville, MD. The VA Office of Research and Development in Washington D.C. has asked Westat to conduct an independent study of how extramural funds received by VA Principal Investigators (PIs) are managed. Today we would like to hear about your experiences as a VA grant holder, working with your academic institution and/or a VA Non-Profit Research and Education Corporation (NPCs).

For this study, Westat interviewers will be speaking with VA PIs across the country, with some in person and some on the phone. We will submit a report to the VA Office of Research and Development in Washington D.C. at the conclusion of the study that explains our findings regarding the current roles of NPCs and Academic Affiliates (AAs) in obtaining and managing extramural funding obtained by VA PIs. The VA ORD will be sharing the results of our report with the House Committee on Veterans Affairs (HVAC). We will not identify you or quote you directly, but it may be possible for readers of the report to identify you as a participant because of your affiliations and status as a PI.

Westat and the VA are grateful for your time and willingness to speak with us. We want to let you know that since this is a research study, we would like you to speak freely and let us know if you cannot answer a question. Please bear with us as some of our questions may seem redundant or awkward. Some answers may seem obvious. If you find that some of the questions we ask do not address your concerns about the management of extramural funding, please feel free to explain what it is you think we need to know.

We have planned for this interview to last not more than [xx] minutes. Do you have any questions at this time? [ANSWER ALL QUESTIONS.]

Finally, with your permission, we would like to record this interview. The recording will help us recall exactly what was said when we go to summarize our findings. Recordings and notes will be stored on Westat's computers and will be available only to the Westat project team. We will destroy the recordings after the study is complete. Are you okay with us recording?

[IF PERMISSION IS GIVEN TO RECORD, ASK AGAIN IF THERE ARE ANY QUESTIONS. ANSWER ALL QUESTIONS.]

If there are no further questions or concerns, I'd like to start the recording now.

[TURN ON THE RECORDER] For the purposes of the recording, I am going to ask you once again if you are you willing to participate in the interview. Can you please confirm?

Are you willing to have the interview recorded? Thank you very much, so now we begin.

1. PRINCIPAL INVESTIGATOR BACKGROUND

    a. Employment and research

        (i) Can you briefly describe your research trajectory and VA employment history?

    b. Academic affiliations

        (i) In addition to your VA appointment, what other academic affiliations do you hold?

        (ii) How is your time split between the VA and the academic affiliate?

    c. Extramural grants

        (i) Please briefly describe the extramural grants for VA projects you have held in the last 5 years.

        (ii) Why has it been it important to apply for and receive extramural grants?

        [PROBE]: Necessary for research agenda, career advancement, other?

        (iii) Have your extramural grants been administered by the VA's NPC or by your academic affiliate? [IF VARIATION] How many by the NPC vs. the affiliate?

2. POLICIES AND PRACTICES FOR THE ADMINISTRATION OF EXTRAMURAL FUNDS

    a. Policy for determining the grant institution

        (i) **Who decides** whether the affiliate or the NPC will administer a research grant? How is the decision made? Please explain the process.

(ii) Are there **local policies or guidelines** (such as an MOU) for deciding where to manage the grant (NPC vs. affiliate)? If there are guidelines, what are they? How are decisions made for each grant?

(iii) How does the policy or grant administration strategy **differ depending on the funding source** (federal, non-profit, or industry)?

(iv) Does the institution where your extramural grant is administrated (NPC vs. affiliate) depend upon the type of research you are conducting? Please explain.

[IF YES, PROBE]: Are clinical trials, animal research, disciplinary differences, private versus federal funded VA projects handled differently? Other types of research? Where are industry sponsored trials administered?

b. Subaward/subcontract policies

(i) If the majority of the work (i.e., greater than 50%) is conducted at the VA, does the NPC administer the funding?

(ii) When the University administers a grant that is partly conducted at the VA, is the NPC subcontracted, or subawarded, the portion conducted at the VA? Explain why or why not.

c. PI's grant institution preferences

(i) [IF NOT YET ADDRESSED]: How much choice do you have on whether your VA project will be administered by the NPC or the academic affiliate? Please explain.

(ii) Do you prefer to manage your grant at the affiliate or the NPC? Why?

3. NPC SERVICES AND BENEFITS

(i) How does your designated NPC benefit the VA?

(ii) [PROBE:] What services does your designated NPC offer to the VA and VA PIs?

4. NPC POTENTIAL

(i) Do you think that your VA's NPC is being utilized to its fullest potential by the VA PIs? Please explain why or why not.

5. ACADEMIC AFFILIATE SERVICES AND BENEFITS

a. What services or benefits does the affiliate provide to the VA? [PROBE]:

(i) Institutional review Boards (IRB)

(ii) Institutional Animal Care and Use Committees (IACUC)

(iii) Institutional Biosafety Committee (IBC)

(iv) Core labs

(v) Pre-award management

(vi) Post-award management

(vii) Off-site research space

(viii) HR employee benefits

(ix) Documentation

(x) Accreditation

(xi) Help with recruitment and retention

(xii) Other?

[IF NOT ALREADY ADDRESSED]

(i) What support does the affiliate provide to VA investigators when submitting federal grants? How does it compares to the support provided by the NPC?

(ii) How do affiliates contribute to the recruitment and retention of VA scientists?

b. Comparing academic affiliate and NPC services

(i) What functions can the NPC perform that the affiliate cannot?

(ii) Are there areas where the NPC is in better position to manage PI grants?

(iii) What are some of the functions academic affiliates can perform that NPCs do not?

(iv) Are there some functions that affiliates can perform more effectively than the NPC? Please explain.

c. Indirect costs

(i) When the affiliate administers a VA PI's grant, how does the affiliate use the grant's indirect fees to benefit the VA (if at all)?

d. Research on veterans

(i) Do you think that your VA's relationship with the affiliate enhances opportunities for research on the veteran population and/or on veteran health?

(ii) In your experience, how often do studies conducted at the affiliate use veterans as subjects?

6. MISALIGNMENT OF THE ACADEMIC AFFILIATE AND THE VA

(i) Do **research policies and procedures differ** across the NPC and the affiliate?

[IF YES]: How do they differ? Are they in conflict?

(a) Does the PI and other researchers experience the conflict? How?

(b) [IF RELEVANT] Who resolves the disagreement?

(ii) Are VA and affiliate policies ever **in disagreement**?

[IF YES]: Which policies? Why is that?

[IF RELEVANT] How are differences managed? Who manages them?

Can you give an example?

(iii) Are **research standards/best practice** guidelines the same at the NPC and the Academic Affiliates?

[IF NO]: How are they different? Can you give an example?

7. CLOSING

(i) Is there anything we haven't already spoken about in regard to VA PIs' extramural grants and their management at NPCs and affiliates that you think would be important for me to know?

Thank you for your time!

Appendix B

Abbreviations

Appendix B
Abbreviations

AA – Academic Affiliate

ACOS-R – Associate Chief of Staff for Research and Development

ACOS-E – Associate Chief of Staff of Education

CDC – Centers for Disease Control and Prevention

CFO – Chief Financial Officer

CRADA – Cooperative Research and Development Agreement

DHHS – Department of Health and Human Services

DOD – Department of Defense

ED – Executive Director

F&A – Facilities and Administrative

IACUC – Institutional Animal Care and Use Committee

IBC – Institutional Biosafety Committee

IPA – Intergovernmental Personnel Act

IT – Information Technology

IRB – Institutional Review Board

MOU – Memorandum of Understanding

NIH – National Institutes of Health

NPC – Nonprofit Corporation

NPPO – Nonprofit Program Office

PI – Principal Investigator

VA ORD – Department of Veterans Affairs Office of Research and Development

RDIS – Research and Development Information System

R&D – Research and Development

VERA – Veterans Equitable Research Allocation

VAMC – Veterans Affairs Medical Center

VHA – Veterans Health Administration

WOC – Work without Compensation