Final Report

Evaluation of the VA Medical Research Program

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Executive Summary

VA Medical Research Program

The Office of Research and Development (ORD) is an organization within the Veterans Health Administration that has a mission of “discovering knowledge, developing researchers and health care leaders, and creating innovations to advance health care for Veterans and the nation.” To fulfill this mission, ORD funds research projects conducted by the investigators at the VA Medical Centers (VAMCs) across the country. The research program is comprised of four Services: Biomedical Laboratory Research and Development (BLR&D); Clinical Sciences Research and Development (CSR&D), which also includes the Cooperative Studies Program; Health Services Research and Development (HSR&D); and Rehabilitation Research and Development (RR&D). In addition to the individual grants, each Service supports larger scale team projects (research centers of excellence) and career development awards.

In FY2010 the ORD research budget was $581 million; these funds support approximately 2,000 Principal Investigators who form the core of the VA research community. By ORD estimates, an additional 5,000 researchers are not funded by ORD, but use VA facilities, equipment, or access to patients.

Study Goals

Abt Associates was awarded a contract with the Office of Policy and Planning (OPP) to conduct an evaluation of the VA medical research program. This evaluation included two phases. Phase I was devoted to answering 13 Research Issues identified by VA for the study, which spanned various program processes, structure, management, and outcomes. These Research Issues were as follows:

- R-1: Provide a comprehensive description and analysis of each Service
- R-2: Determine the factors that facilitate medical research innovation
- R-3: Evaluate quality and impact of VA research
- R-4: Analyze how VA communicates information on research studies
- R-5: Identify comparison programs and compare/contrast by common key metrics
- R-6: Analyze funding for the past six years
- R-7: Determine VA researchers’ perspective on key organizational issues
- R-8: Evaluate the coordination of human subject review process
- R-9: Evaluate IT standards
- R-10: Evaluate environmental protection processes
- R-11: Compile a roster of medical research staff
- R-12: Evaluate VA policy for granting access to its medical facilities
- R-13: Analyze the possible effects of Super Center concept on research and recruitment.

The findings from Phase I were documented in the interim report and presented to the OPP and ORD leadership. Two problems were selected for further analysis and resolution in Phase II.

Methodology

Abt Associates’ approach to the evaluation of the research program included three data collection methods. The first step in the evaluation was to identify and interview senior individuals knowledgeable about the program. This group included ORD leadership, representatives from the Office of Information Technology and from the Office of Research Oversight, directors of cross-ORD programs such as communications and technology transfer, research directors at the VA medical facilities, Research
Centers of Excellence Directors, academic researchers and senior administrators, representatives from Veteran service organizations, members of the National Research Advisory Council (NRAC), and peer reviewers. Interviews were also conducted, for the second phase of the project, with program managers and leadership at other federal agencies. A total of 65 individuals were interviewed.

In addition, OPP and ORD provided us with dozens of program-related documents and datasets. These included strategic plans, handbooks, funding solicitations, reports to NRAC, administrative reviews, reports by the Office of Inspector General, newsletters, program booklets, Veteran demographic data, and many other items.

The cornerstone of the data collection was an on-line survey of the VA researchers. The goal of the survey was to collect systematic information on the research program infrastructure, processes, outcomes, and participant characteristics. The groups surveyed included nearly 2,000 ORD-funded Principal Investigators, directors of research centers, Associates Chiefs of Staff for Research and Development, and site investigators in the Cooperative Studies Program. The survey was implemented in May–July of 2011 and the response rate was 52%.

**Phase I Findings**

The direction of the VA research program is influenced by many factors: its mission, input from Congress and Veteran service organizations, changing Veterans’ needs, interests of the research community, and scientific opportunities. While VA research is largely investigator-initiated, ORD has tools at its disposal to shape the research portfolio. These tools include setting and communicating ORD’s funding priorities to the research community, using requests for proposals to support specific research topics, funding centers of excellence to develop capacity in particular areas, and establishing long-term, large-scale initiatives such as the Million Veterans Program. However, ORD is also limited in its capacity to steer research by the interests and expertise of its researchers and by its commitment to the traditional peer review process, which favors research technical quality and feasibility above all other aspects of the proposal, including mission relevance. The process of funding allocations is monitored by the National Research Advisory Council (NRAC), which is responsible for ensuring that VA maintains its focus on the Veterans’ needs, yet supports a balanced portfolio of basic, applied, rehabilitation, and health services research. In the interviews, NRAC members said that ORD was successful in steering and balancing the program.

Support for VA research comes from several principal sources: research appropriations, the Veterans Equitable Resource Allocation (VERA) system, and other federal and non-federal agencies and entities. We found that research appropriation continued to increase over the past six years, at 8% on average, to reach an estimated $581 million in FY2010. The VERA funding almost doubled over this period. In contrast, funding support from other federal and non-federal sources remained flat or declined. However, even in the present environment of decreasing federal funding, VA researchers leveraged $710 million in grants from the National Institutes of Health (NIH), the Department of Defense (DOD), and the biotech and pharmaceutical industries in FY2010, or $1.2 per each dollar of Congressional appropriations. Over the past six years, ORD funded between 1,600 and 1,800 grants per year.

The Veterans Health Administration serves Veteran populations with different health care needs. Some Veterans require treatment for conditions associated with aging, such as most cancers, degenerative diseases, and cardiovascular diseases, while others are returning from current conflicts and require care for war wounds. Examination of funding data by disease and condition for FY2010 showed that ORD maintains a balanced portfolio between deployment-related research and research on the diseases associated with aging.
To assess the impact of the research program, we collected data both on the traditional indicators of research productivity and quality and on the benefits of the program to Veterans. We found that in 2010 there were nearly 7,000 publications listing a VA address, which were cited almost 17,000 times. ORD-funded PIs published on average 1.5 papers per year, a rate similar to NIH-funded investigators. The papers appeared in journals with high impact factors. Also in 2010, ORD received 10 patents and 169 licenses and filed 31 patent applications. The federal clinical trials database reported 28 Phase IV clinical trials conducted by VA, of which 11 were marked as completed. It should be noted that this is not a definitive list of all clinical research funded by ORD.

To examine additional benefits of VA research, we developed a set of indicators for scientific, clinical, public health, and quality of life impacts, and collected data for these indicators using the survey of VA-funded investigators. A significant number of VA researchers reported that their work has resulted in improved understanding of the disease mechanism; identification of unknown side effects of a clinical intervention; initiation of clinical trials and the use of a new drug, regimen, treatment, or disease management approach; better patient and provider education; improvements in patient life expectancy and quality of life; reduction in health care costs; and development of new devices to help disabled Veterans.

One of the reasons for establishing the research program at VA in the 1920s was to attract academic clinicians to the VA system. Our study revealed that the research program is an important recruitment tool. In the survey, 87% of respondents believed that the program was important or very important to the recruitment and retention of talented clinicians to VA. In addition, the vast majority of researchers said that research was a factor in their decision to come to (78%) and to remain at (92%) VA.

Based on the interviews and the survey, we also identified several weaknesses which, if addressed, would improve productivity of the research program and enhance its value to VA. One of the problems that emerged strongly from the evaluation was excessive regulatory burden on the community and the culture of enforcement over education. We found, for example, that researchers spent on average 10% of their time on compliance with federal, affiliate, and VA-specific regulatory requirements. This time commitment was very significant, especially when placed in the context of other duties: for example, an average VA-funded investigator spent 38% of their time on research and 18% of time on clinical duties. In the survey, 69% of respondents expressed dissatisfaction or strong dissatisfaction with the amount of time spent on research compliance and 58% expressed dissatisfaction or strong dissatisfaction with the frequency of the required training for research.

Another area of significant dissatisfaction in the research community was information technology (IT) support, which does not appear to meet researcher needs. The problems reported included lack of customer orientation, delays in the provision of support, inadequate access to equipment and tools, and inflexible data access policies. In the survey, 65% of respondents disagreed or strongly disagreed with the statement “the Office of Information Technology understands research needs,” and 34% reported delays in the initiation of research projects that resulted from inadequate IT support. The vast majority (72%) described policies and procedures for purchasing IT equipment as insufficient.

The research community also reported problems with contracting and hiring processes. For example, 71% reported dissatisfaction with hiring, 66% with the length of time to obtain Without Compensation appointments, and 58% with the time needed to obtain access to VA facilities for students and interns. In the survey, we measured the length of time that was required for various research-related activities. We found that for 67% of respondents it took at least one month and up to nine months to obtain a without compensation appointment for a researcher coming to their group. For 16% it took more than 10 months to execute a contract for research-related products or services.
Finally, the research community indicated the need for greater funding support. In the survey, 59% disagreed with the statement that ORD funding levels were adequate and 35% that the duration of funding was adequate. More than half were dissatisfied with the availability of travel funds.

**Phase II Findings**

Based on the results of Phase I, VA selected two problems for further analysis and potential resolution:

1. *How can VA reduce and refine the regulatory burden in order to enhance research innovation and productivity?*

2. *Given a potential reduction in funding for research in future years, what strategy should ORD use to allocate limited research funding to best meet the anticipated needs of Veterans over the next five years (2014–2019)?*

For Problem 1, regulatory burden, we focused on three areas of concern that emerged most strongly in the survey of VA investigators: human subjects protection, data access and sharing, and training. For each area, we analyzed the origins of the burden, its extent, and potential approaches mitigating the problem.

To examine the appropriateness of VA rules related to the participation of human subjects in research, we compared the VA requirements to the so-called “Common Rule,” the set of principles that governs protections of research subjects. We found that VA has introduced a number of seemingly unnecessarily additional administrative, oversight, and reporting requirements that do not offer additional protections to Veterans participating in research, but rather weaken the authority of the Institutional Review Boards and cause delays in the initiation of research. We also found that lack of clear definitions for which types of data are sensitive and should be safeguarded was at the root of many IT problems experienced by the research community. In contrast to VA, the NIH manual for intramural investigators explicitly lists examples of non-sensitive research data.

Our examination of VA training requirements obtained from one of the medical centers revealed that 36 courses must be taken annually by at least some staff and 24 by all staff. This number does not include the requirements imposed by the affiliate institutions. We also found that VA does not have a system in place to determine who needs to complete a course, whether this course is relevant to their duties at VA, and if they already have the knowledge being conveyed. The frequency of the courses also seemed excessive. Based on the survey of VA researchers, who reported spending 10% of their time on compliance-related activities, we estimated that the cost of complying with all regulatory requirements for research staff stands at $104 million per year.

To identify the most appropriate funding strategies, the goal of Problem 2, we took a multi-pronged approach. First, using a variety of indicators we examined program performance by Service and by disease area, which represent two potential options for funding allocation decisions. We observed that differences in performance were consistent with each Service’s mission: for example, a higher than average number of PIs affiliated with the rehabilitation Service reported that their research resulted in devices for Veterans. We did not find clear differences when performance was examined by disease focus. The second part of our approach was to determine how the VA research portfolio currently maps onto VA health care expenditures. Finally, using historical expenditures and demographic trends, we identified growing areas in the utilization of health care, which we argue could be targeted for funding. In parallel, we interviewed senior administrators at several agencies that fund scientific research to learn what approaches they use to make decisions on the direction of their programs.
We found very good correspondence between the diseases for which Veterans seek care and the number of research projects focusing on these diseases. Our analysis of demographic data indicated that the number of Veterans aged 75 and older and the number of women Veterans is expected to increase in the next 20 years. Arguably, ORD may want to continue investing in the research on the diseases and conditions which are prevalent, costly, or growing in these two groups. Analysis of ICD-9 codes over the past several years revealed that these included diseases of musculoskeletal, circulatory, and nervous systems, and cancer (prevalent in elderly) and infectious diseases and childbearing-related conditions (prevalent in women). ICD-9 data also showed that homelessness and unemployment (which are coded as health-related conditions by VA) are also on the rise, although we understand that other data collection activities at VA indicated decline in homelessness.

Using our researcher survey, data on NIH funding, and analysis of publications, we examined the frequency of various outcomes by Service. The results were consistent with the mission of each Service: for example, BLRD performed significantly better than average on the discovery of knowledge indicators and RRD on the quality of life indicators.

Finally, by investigating how other federal funders make decisions on research priorities, we found that some agencies use more systematic and transparent process than what we observed for ORD.

**Recommendations**

Based on the in-depth examination of the VA medical research program, we make the following recommendations.

- ORD and the Office of Information and Technology (OI&T) should collaborate to improve IT support services to the research community
- OI&T should re-evaluate and clarify their policies and procedures for data access and sharing
- VA should make its training requirements more targeted and less frequent
- ORD should bring the human subjects protection program in line with national standards
- ORD should improve the transparency and inclusiveness of its strategic planning process
- ORD should establish a research outcome data collection and grant management system
- ORD should continue to support and possibly increase funding for the research on diseases which afflict or are expected to afflict elderly and women Veterans. ORD should continue to invest in research to combat homelessness and unemployment among Veterans.
Chapter 1: Introduction

In November 2011, Abt Associates was awarded a contract with the Office of Policy and Planning to conduct an evaluation of the Medical Research Program at the US Department of Veterans Affairs (VA). Phase I of the study was devoted to collecting data on program processes, structure, management, and outcomes. In Phase II, two of the problems identified in Phase I were selected by VA for further analysis and resolution. This report describes the findings which emerged from both phases of the study and our recommendations for how to make the program better meet the needs of the research community and the Veterans.

VA Medical Research Program Mission and History

The mission of the medical research program is to “improve the lives of Veterans—and ultimately all Americans—through health discovery and innovation.”¹ The program began in the early 20th century and has gone through a remarkable transformation from a small group of physicians interested in research to a dedicated workforce of thousands of biomedical scientists, engineers, economists, health services researchers, and research administrators who serve in the program today.

The early years, 1925–1955

The origins of the medical research program go back to 1925, the year that marked the establishment of diagnostic clinics and subsequently the first publications of research results in the US Veterans’ Bureau Medical Bulletin.² The focus of the nascent program, shaped by World War I, was on tuberculosis, psychiatric disorders, and cardiovascular disease. Until 1932, the Veterans’ Bureau (what became the Department of Veterans Affairs) made no effort to establish funded research units. The investigators in the late 1920s either volunteered their time to conduct research “on a shoestring” or found a way to divert resources available to them for clinical work to support research.³

The Tumor Research Laboratory established in 1932 at the Hines VA Hospital in Chicago was the first entity to receive dedicated funding for research from the Central Office. The Neuropsychiatric Research Laboratory at the Northport VA Hospital and the Cardiovascular Research Unit at the Washington DC VA Hospital were created shortly thereafter. Together, these three laboratories formed the nucleus of the research program. Staff at these laboratories carried out research on testicular tumors, epilepsy, and coronary disease.

Between the mid-30s and mid-40s the program was in decline. World War II took its toll: during the first year of the war alone VA lost 7,000 employees. Shortages in staff physicians and a growing reputation for inferior medical care forced VA leadership to take action. The result was the passage of Public Law 293 in 1946, which established the Department of Medicine and Surgery within VA and gave VA formal responsibility for providing medical care to the Veterans. Under the new law, physicians leaving the military could be quickly hired into the VA system. Another important development for the research

¹ VA Research and Development Strategic Plan 2010–2014.
³ Margaret T. Hays. A Historical Look at the Establishment of the Department of Veterans Affairs Research and Development Program. 2010.
program during this period was the growth of academic affiliations, which provided VA with access to talented medical staff.

VA made two important contributions to biomedical research during the post-war years. One was the development and testing of tuberculosis therapies, which not only improved disease outcomes for the patients, but also pioneered the concept of large-scale, randomized controlled clinical trials which is the norm today. Research on tuberculosis led to the establishment of the Cooperative Studies Program (CSP), the branch of VA conducting clinical trials. During this period, VA researchers pioneered the use of radioactive isotopes for diagnosis and treatment of disease, which ultimately earned them a Nobel Prize and gave rise to the field of nuclear medicine.

VA physicians hired through medical school affiliations had a wide range of scientific interests which included bench research. VA hospitals, however, had not been designed to house research labs, and did not have adequate space, equipment, or staff. Hospital managers who had no research background did not appreciate the benefits of research to VA or to Veterans. Furthermore, existing regulations prohibited investigators from accepting research support from outside sources, significantly limiting the capacity of the research program. These problems were well known to Harold Welt, the VACO Chief of Research at the time, who did what he could to mitigate them. Garages and closets were converted into laboratories at the existing buildings and new construction plans were revised. Because of various budgetary and regulatory constraints no construction or renovation project could exceed $15,000. The only exception to these small, ad hoc efforts was the construction of the state-of-the-art Chicago Lakeside VA Medical Center, which had an entire floor built specifically to house research labs.

Eventually VA leadership efforts to promote a research program paid off. In 1951, VA scientists published more than 800 papers, compared to fewer than 100 in 1946. By 1952, 66 facilities at VA had medical research programs and almost 400 staff was salaried from research set-aside funds. VA lobbying of NIH resulted in a key policy change in 1954: VA investigators were now eligible to compete for NIH funds through affiliate institutions. In 1955, Congress finally appropriated a budget for VA research. The program had come of age.

**Program expansion, 1955–1970**

In the 20 years that followed, scientific research at VA flourished. The Cooperative Studies Program (CSP) continued to build on its early success with tuberculosis trials. In the mid-1950s, it expanded to include studies of other pulmonary diseases and of the effects of tranquilizers on tuberculosis patients. The crown jewel of CSP was the study of treatments for hypertension, which brought a Laskar Award and a Nobel Prize nomination to Edward Freis at the Washington, DC Medical Center. Two years later, Ludwig Gross at the Bronx VA won another Lasker Award for the “discovery of leukemia and cancer-inducing viruses in mammals.” Other famous VA contributions included the cardiac pacemaker (1958), concepts that led to the development of the CAT scan (1960), and liver transplantation (1968). In 1977, two VA researchers achieved the highest honor – Nobel Prizes in Physiology and Medicine for the “discoveries concerning the peptide hormone production of the brain” (Andrew Schally, New Orleans VA Medical Center and Roger Guillemin, Salk Institute) and “for the development of radioimmunoassays of peptide hormones” (Rosalyn Yalow, Bronx VA Medical Center).

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As the reputation of the program grew, so did its operating budget. Congressional allocations increased and research space was built or renovated. In addition, VA researchers used their ties to academic affiliations to leverage extramural research support. The Associate Chief of Staff for Research position was established, in part to oversee funding and support now provided by the Central Office. Unlike today, however, responsibility for proposal review and allocation of funding at the time rested with local Research and Development Committees.6

In the late 1960s and 1970s the VA research program entered a period of turmoil. Funding shortages became so dire that in 1979 VA was planning to terminate virtually all of its small research programs as part of the initiative that came to be known as “project scissors.” Fortunately, a last-minute increase in the federal budget prevented this drastic step. Decreasing federal budgets and concerns expressed by the National Academies of Science about the process of funding allocations forced VA leadership to reconsider its peer review mechanisms. Reluctantly, VA adopted its present merit review system, modeled after the NIH extramural funding process.

Maturity and recognition, 1970–1999

Two notable organizational changes took place over the next 20 years. In 1971, VA reviewed its hospital operations and identified greater need for health services research. The Health Services Research Service was quickly established, with Leon Bernstein as its first director. The first project taken up by the Health Services Research and Development group, consisting of 125 scientists, was to design and install a comprehensive information technology system across the agency. It quickly emerged, however, that HSR&D researchers lacked the necessary expertise and the assignment was moved to a separate office in 1976. HSR&D did not have its own budget until 1977, when the Service was codified in the VA legislation. The 1977 HSR&D budget was $3.6 million, and it remained mostly flat until 1983.7

The biggest challenge faced by HSR&D was recruiting sufficient research staff. Carleton Evans, who took over from Bernstein in 1972, tried several strategies to grow the program. Proposal review committees provided technical assistance to aspiring health services researchers during application submission. In addition, VA formed affiliations with UCLA, Johns Hopkins, MIT, Yale, the University of Pennsylvania, and other top universities around the country. In 1975, the National Center for Health Services Research issued a solicitation for research centers that would offer research and training programs in health services. When VA affiliates were awarded the grant, VA received funds to establish several small units. Research programs at these VA units were expected to grow through leveraging of funding from other sources. While the program sponsored by the National Center ended in 1980, by then VA had built sufficient capacity to establish its own Centers of Excellence in Health Services Research.8

The second change occurred in the area of rehabilitation research. Prior to the establishment of the rehabilitation program in the mid-70s, VA responsibility for prosthetics and sensory aids resided within the clinical service, and all research in this area was funded through contracts with outside vendors. In 1973, Thomas Newcomb became the head of the newly reorganized ORD. Newcomb believed in raising the status of the rehabilitation program and he sought the support of the Veteran service organizations in elevating the program to the status of a Service. His efforts bore fruit in 1976, when the Prosthetics Research Program was transformed into the Rehabilitation Engineering Research and Development

6 Margaret T. Hays. 2010.
7 Ibid.
8 Ibid.
Service (RR&D). The RR&D budget increased from approximately $3 million in 1976 to over $8 million in 1980. To develop in-house expertise in rehabilitation research, Newcomb steered RR&D away from its contractual mode of operation. By 1980 the majority of research supported by RR&D was conducted at VA or involved VA investigators. Like Evans with HSR&D, Newcomb used academic affiliations and center mechanisms to increase research capacity in rehabilitation research.

From the 1970s through the 1990s, VA made substantial contributions to biomedical research, both basic and in clinical areas. Some of the highlights of this period included the design of the nicotine patch (1984), development of a functional electrical stimulation system\(^9\) (1991), and identification of a schizophrenia associated gene (1994).\(^{10}\)

**Modern era, 2000–2011**

The invention of technologies to mine entire genomes for information opened up novel and exciting directions in biomedical research. The VA research community embraced this new science. For example, in 2009 VA launched one of the largest studies to date on the genetics of schizophrenia and bipolar disorder. The study will involve 28,000 Veterans. In 2010 VA announced the Million Veterans Program, a study which will examine the relationships between genes and health outcomes on an unprecedented scale. The notable scientific achievements for this period include demonstration of the effectiveness of a new vaccine for shingles (2005), identification of a potential biomarker for PTSD (2010), development of an artificial lung prototype (2011), and bringing a bionic prosthetic ankle into clinical use (2011).

At present, the VA research program spans four Services: Biomedical Laboratory Research and Development (BLR&D), Clinical Science Research and Development (CSR&D), Health Services Research and Development (HSR&D) and Rehabilitation Research and Development (RR&D). Approximately 2,000 Principle Investigators receive funding support from ORD and form a core of the research community. By ORD estimates, an additional 5,000 researchers use VA facilities, equipment, or access to patients.

**Organization of the Report**

This concludes our introduction to the medical research program. In Chapter 2 we describe methodologies used in this study. Following are the study findings related to program organization and governance (Chapter 3), research funding and partnerships (Chapter 4), research infrastructure (Chapter 5), and research results (Chapter 6). These chapters include all of the information collected in Phase I of the project. Chapter 7 describes the two problems chosen by VA for further study and our findings resulting from more in-depth examination of these topics. Chapter 8 presents our conclusions about the VA research program and recommendation to VA.

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\(^9\) The system that allows paralyzed patients to move their limbs.

\(^{10}\) State of VA Research. 2011.
Chapter 2: Methodology

In this chapter we describe our approach to data collection, including identification and recruitment of interview and survey respondents, types and sources of extant data used in the study, and procedures for fielding the survey of VA researchers.

Key Informant Interviews

We took advantage of several sources to identify individuals to interview. First, we used contacts suggested by ORD (at the kick-off meeting, we were provided with an initial list of 29 individuals in leadership positions at ORD). Within the first few weeks of the project, we interviewed ORD and Services leadership to understand their vision and goals for the program as well as key challenges faced by the research community. We also spoke with ORD staff in charge of communications, technology transfer, and human subjects protection programs. When we became relatively familiar with the overall structure and management of the program, we asked ORD to identify several Associate Chiefs of Staff for Research (referred to as ACOS in this report) from a diverse set of medical centers, to help us understand the field perspective. ORD suggested 10 ACOS, selected from large and small facilities as well as from among experienced and new ACOS. Furthermore, ORD chose individuals known for their frank and forward manner, to make sure that we heard about the problems, as well as the successes, that researchers face on the ground. In addition to ACOS, ORD recommended a few directors from the Research Center of Excellence and from QUERIs, chosen using similar criteria.

We also spoke with a number of respondents knowledgeable about the program, but not employed by it. These individuals were recruited from among our own contacts or were recommended by ORD. This group included members of the National Research Advisory Committee (NRAC), leaders of Veteran service organizations, and senior administrators and university researchers. The goal of speaking with this group was to obtain an external, potentially more objective perspective on the program.

As our understanding of the program grew, we continued to interview additional informants who could further clarify or expand our knowledge of various aspects of the program. For example, to better understand VA-DoD relationships, we spoke with the Deputy Director for Deployment Health, who is closely involved in developing and maintaining the relationship between these two organizations. We also conducted additional interviews with the same individuals, for example with HSR&D leadership, to collect data on the organizational changes that are taking place within the Services. Finally, interviews were conducted in the second phase of the project, to further understand the nature of the regulatory burden and to identify allocation strategies used by other funders.

To achieve a balanced understanding of the program, we made every attempt to consider diverse points of view. For example, when the consensus view from the field began to emerge that researchers are subject to excessive regulatory burden, we reached out to the Office of Regulatory Oversight, to give staff enforcing and monitoring compliance an opportunity to explain their position.

We requested an interview from 65 individuals; 56 interviews were conducted (not counting multiple conversations with the same persons), for an overall response rate of 88%). The number of interviewees by group is shown in Exhibit 1.
### Exhibit 1. Number of interviewees by group

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORD leadership and staff</td>
<td>19</td>
</tr>
<tr>
<td>VA staff</td>
<td>5</td>
</tr>
<tr>
<td>ACOS and Administrative Officers</td>
<td>11</td>
</tr>
<tr>
<td>Research CoE Directors</td>
<td>3</td>
</tr>
<tr>
<td>VA researchers</td>
<td>3</td>
</tr>
<tr>
<td>QUERI Directors</td>
<td>2</td>
</tr>
<tr>
<td>Academic researchers, administrators, and</td>
<td>9</td>
</tr>
<tr>
<td>professional societies</td>
<td></td>
</tr>
<tr>
<td>VSO</td>
<td>2</td>
</tr>
<tr>
<td>NRAC</td>
<td>2</td>
</tr>
<tr>
<td>Peer reviewers</td>
<td>2</td>
</tr>
<tr>
<td>Other federal funders</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>65</strong></td>
</tr>
</tbody>
</table>

*Source: Abt Associates.*

Our team developed all interview questionnaires for the study. All respondents received the questions in advance of the interview, in order to give them time to consider the questions. To reassure respondents employed by VA, ORD introduced us and the study and requested an interview. This request was followed by an email from an Abt researcher to arrange the time. The interviews with ORD leadership and with the leadership of the Jamaica Plain facility in Boston were conducted in person and all other interviews by telephone.

In the beginning of the interview, we explained the goals of the study and the reason for the interview. Respondents were also given assurances that they would not be quoted by name in our report. All interviews were semi-structured in nature, with the interviewer steering the discussion to make sure that all the topics were covered, while at the same time allowing the respondents to expand on the topic as they wished and to take the conversation in a new direction. In our experience, this interviewing style is particularly appropriate for senior educated professionals very knowledgeable about the subject being discussed. We probed extensively and asked for examples to obtain as much information as possible on each topic.

The interviews were conducted by a small number of experienced researchers familiar with the subject. Most interviews lasted for 1–1.5 hours. A research assistant took notes during the interviews and these notes were reviewed by the interviewer for accuracy. Interview procedures were reviewed and approved by the Abt IRB.

**Document Analysis**

The Office of Policy and Planning (OPP) and ORD provided us with dozens of program-related documents. These included strategic plans, handbooks, funding solicitations, reports to the National
Research Advisory Council, administrative reviews, reports by the Office of Inspector General, newsletters, program booklets, and many other items. In addition, we requested and obtained from ORD various other documents and data that we needed to respond to the Research Issues. For example, ORD staff provided us with budget data for the past six years, statistics on outreach and knowledge transfer activities, internal analyses of research funding by common Veterans’ conditions, organizational charts, instructions to merit reviewers, and presentations to the field, just to name a few. We reviewed all of these documents; sources supporting our findings are referenced in this report.

ICD-9 and Demographic Data

The Allocation Resource Center at VA provided us with six years of ICD-9 data,\(^1\) including expenditures, number of patients, and number of inpatient and outpatient visits by ICD-9 code. These data were used to examine expenditure and patient volume trends over time to identify the most prevalent and fastest growing diseases and conditions affecting Veterans. Demographic projections data were downloaded from the VA web site.

Survey

The key element of our data collection was an on-line survey of VA-funded researchers. The population of VA researchers is large and heterogeneous and we had several discussions with OPP and ORD about who to include in the survey. The details of the selection process are described in the Technical Appendix. The decision was ultimately made to survey the following individuals:

- Principal Investigators funded by ORD
- ACOS at medical centers with research programs
- Cooperative Studies Program (CSP) site investigators
- Research Centers of Excellence (CoE) directors
- Research Enhancement Award Program (REAP) directors.

The initial survey sample included 1,964 individuals for whom email addresses and telephone numbers were provided by VA.

The survey instrument was developed in several stages and was based on the data collected in interviews and the preliminary analysis of program documents (Exhibit 2). In addition, we formulated some of the questions to match a similar survey of researchers conducted in 2000, so that we can analyze changes in the program over time. We also reviewed survey items developed by others to measure creativity and innovation in organizations and included similar questions in our survey. In order to ensure that all research questions that could be addressed in the survey were covered, we maintained a cross-walk document linking the survey items to the Research Issues.

The initial draft underwent several rounds of revisions to incorporate suggestions from ORD and OPP (Step 1). The resulting survey was reviewed by four members of the Abt Advisory Panel (Step 2). All Panel members were provided with a background document describing the goals of the evaluation, the VA medical research program, and the Research Issues that we were studying. The Panel members were positive about the instrument and recommended only a few minor changes.

\(^{11}\) ICD-9 stands for “International Statistical Classification of Diseases and Related Health Problems, Ninth Revision”
Exhibit 2. Development of the on-line survey

<table>
<thead>
<tr>
<th>Survey development step</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: Instrument development</td>
<td>Multiple drafts with significant changes</td>
</tr>
<tr>
<td></td>
<td>to the instrument</td>
</tr>
<tr>
<td>Step 2: Review by the Advisory Panel (N=4)</td>
<td>Minor changes to the instrument</td>
</tr>
<tr>
<td>Step 3: Pilot testing by Abt researchers not involved in the study (N=4) and by former</td>
<td>Minor changes to the instrument</td>
</tr>
<tr>
<td>ACOS (N=1)</td>
<td></td>
</tr>
<tr>
<td>Step 4: Survey programmed and tested by the Abt Team, OPP, and ORD</td>
<td>Minor changes to the instrument</td>
</tr>
<tr>
<td>Step 5: Survey pre-released to a group of VA researchers (N=12)</td>
<td>No changes to the instrument</td>
</tr>
</tbody>
</table>

Source: Abt Associates.

The survey was then pilot tested by four mid-level and senior Abt researchers not directly involved with the project but with experience in research program evaluation and by former ACOS working at the ORD headquarters (Step 3). All pilot testers were requested to record the time it took them to complete the survey and to take note of any questions that were unclear. Several changes to the instrument were suggested and most of these were made. The average time to complete the survey was 29.6 minutes, within the range of our goal of 25–45 minutes.

This draft was transferred to our survey group, which reviewed it for clarity and flow (Step 4). The Abt PD and the survey director had extensive discussions about the best way to present the questions, which answers should and should not be optional, how to remind respondents to complete omitted questions, how to make the questions most time-efficient, the permitted length of open-ended answers, and what text and pictures should be included in the survey. After consultations with OPP and ORD we decided to not include the VA logo in the survey to avoid giving respondents an impression that the survey was managed by VA. Respondents were also assured of anonymity, as VA would receive only aggregated survey data. The programmed survey was shared with OPP and ORD, so that they could see how it would appear to respondents, and for their review and input.

Finally, the programmed survey was pre-released to 12 respondents selected from one of the medical centers (Step 5). Respondents were chosen to represent survey subpopulations and included one ACOS, two VA-funded PIs from each Service, two CSP investigators, and one research CoE director. The response rate for this group was 50%. Based on the pre-release data, we determined that all skip patterns, multiple choice options, and other aspects of the instrument worked properly. No additional changes were made to the survey prior to full release (answers from these respondents were combined with all other answers). Exhibit 3 shows a screen shot of the survey as it appeared to respondents.

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12 This group included two researchers from HSR&D, BLR&D, RR&D, and CSR&D, an ACOS, two CSP site investigators, and one Center of Excellence director.
Exhibit 3. Survey screen as it appeared to respondents

On May 26 2011, ORD sent an email to all ACOS in the facilities with the research programs asking them to alert VA-funded researchers in their facilities about the survey. On May 31, 2011 the survey was released to the field. The survey was closed on July 21, 2011.

Our initial sample included 1,969 individuals (Exhibit 4). In question two, respondents were asked to select their role from one of several categories. Individuals who choose “none of the above” exited the survey and were considered ineligible – “screened ineligible” in Exhibit 4. The size of the sample corrected for ineligibles was 1,907 (1969–62). Of these eligible individuals 1,016 completed and 18 partially completed the survey, for a total of 1,034. The final response rate was 54.2% (1,907/1,034). Exhibit 4 also shows that the response was highest among ACOS and lowest among CSP site investigators. We could not determine response rates for the Research CoEs and REAPs, because we do not know the initial number of respondents in the sample.

Source: Abt Associates.
### Exhibit 4. Response rates

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting sample</td>
<td>1,969</td>
</tr>
<tr>
<td>Screened ineligible</td>
<td>62</td>
</tr>
<tr>
<td>Corrected sample</td>
<td>1,907</td>
</tr>
<tr>
<td>Completed</td>
<td>1,016</td>
</tr>
<tr>
<td>Partial</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total completed + partial</strong></td>
<td><strong>1,034</strong></td>
</tr>
<tr>
<td><strong>Response rate</strong></td>
<td><strong>54.2%</strong></td>
</tr>
</tbody>
</table>

**Response rate by group**

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORD-funded researchers (N=1,566)</td>
<td>815 (52%)</td>
</tr>
<tr>
<td>ACOS (N=109)</td>
<td>86 (79%)</td>
</tr>
<tr>
<td>CSP site investigators (N=247)</td>
<td>92 (37%)</td>
</tr>
<tr>
<td>Research CoE/REAP directors (number unknown)</td>
<td>41 (cannot determine)</td>
</tr>
</tbody>
</table>

Source: Abt Associates.

Research CoE = Research Centers of Excellence
ACOS = Associate Chief of Staff for Research
CSP = Cooperative Studies Program
REAP = Research Enhancement Award Program

Seven reminders from Abt and from ORD were necessary to achieve a response rate of 54.2%. Based on informal feedback from the field, we believe that there are several reasons for our challenges in raising the response rate. First, the researcher community is extensively and frequently surveyed. For example, we learned too late that two other surveys were being conducted in parallel to ours (an annual employee survey and a survey of a subset of researchers about their views on peer review). As we had a tight project schedule, we were unable to delay our data collection efforts.

Second, at least one respondent expressed doubt that any positive changes would result from our evaluation. The respondent noted that none of the past surveys produced any improvements. We communicated this view to ORD and ORD staff sent an email to all ACOS reassuring them that evaluation results would be communicated to the individuals at VA and outside of VA who are in a position to effect change. ORD staff emphasized that a high response rate on the survey was important to the credibility of the data.

Third, the timing of the survey release was not optimal because it was close to the due date for merit applications due in mid-June. Again, lack of knowledge about this conflict and a tight schedule did not permit us to change the timing of the release. Our solution to this problem was to keep the survey open for longer than anticipated to allow respondents more time to complete it.

Finally, we also learned during the fielding stage that many VA researchers prefer to use their academic accounts and may rarely check their VA email. To ensure that our survey reached them, we decided to
identify as many academic addresses as we could for non-respondents. To do that, we used the public NIH database Reporter, which can be searched for all PIs who recently received funding from VA. Approximately 200 addresses were obtained in this way. In addition, we performed Google searches using PI names as queries. Telephone area codes provided to us by VA data and physical locations of respondents, which could be inferred from station numbers, helped us ensure that we found the right individuals. With this method, we were able to identify another 800 or so addresses. Invitations containing survey links were then sent to all academic address in our possession. Of all completed surveys, 79% came from the VA address and 21% from the academic address (data not shown). Exhibit 5 shows the number of completed surveys by date.

Exhibit 5. Number of complete surveys by date

![Number of respondents by survey date]

Source: Abt Associates.
Chapter 3: Program Governance and Organization

In this chapter we introduce the reader to the VA research program structure, management, and oversight. Also included is a description of the general characteristics of the research community.

Leadership and Oversight

The Office of Research and Development (ORD, often referred to by field personnel as "Central Office") is an organization within the Veterans Health Administration (VHA) that has a mission of discovering knowledge, developing researchers and health care leaders, and creating innovations to advance health care for Veterans and the nation. ORD is comprised of four research Services: Biomedical Laboratory Research and Development (BLR&D), Clinical Sciences Research and Development (CSR&D), Health Services Research and Development (HSR&D), and Rehabilitation Research and Development (RR&D).

The ORD headquarters is located in Washington, DC. The program is led by the Chief Research and Development Officer (CRADO), who is supported by two Deputy CRADOs. In addition, each of the four Services is headed by a Service Director. The Central Office has several functions. First, it identifies funding priority areas based on perceived Veterans’ needs, state of research, input from Congress and Veteran service organizations (VSOs), and guidance from the National Research Advisory Council (NRAC). Second, the Central Office develops policies and procedures related to research, for example, how to apply for intramural funding or how to cite VA in publications. Third, ORD is responsible for allocating federal budget appropriations to the four Services and to special programs and initiatives. Finally, ORD leadership maintains regular communication with its various stakeholders and partners, including Congress, VSOs, industry, and other federal agencies.

Research at VA is carried out in 109 VA Medical Centers or VAMCs. Each medical center has an Associate Chief of Staff (ACOS) who is responsible for the day-to-day management and oversight of the research program. The ACOS reports to the Chief of Staff. In addition to general oversight of research activities, VAMC directors ensure that research funds are appropriately used and that infrastructure is available for researchers.

Individual VAMCs report to the Veterans Integrated Service Networks (VISNs); each VISN oversees several VAMCs grouped by geographical area. Facility Directors are responsible for arranging appropriate scientific and administrative support for R&D committees and subcommittees and for ensuring that investigators are allocated time to conduct research and that the research community is in compliance with all policies and regulations.

Organization

The research program spans four Services, each with its own mission and goals. Most researchers are funded by and affiliated primarily with one Service.

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13 http://www.research.va.gov/about/.
14 ORD data.
Biomedical Laboratory Research & Development

BLR&D is the largest Service within ORD. This Service has the highest number of ORD-funded investigators (N=787, data not shown). According to BLR&D leadership, the emphasis of the Service is on pre-clinical development: two-thirds of the projects supported by the Service use human tissues and the remaining use animal models. Current BLR&D projects include genetics and genomics research, proteomics, and studies of cellular dysfunction.

An important recent development for BLR&D is the launch of a large-scale project called the “Million Veterans Program” (MVP). The goal of the MVP initiative is to collect blood samples from one million Veterans and to ultimately link genomic information derived from these samples to phenotypic and medical information stored in their electronic medical records. NRAC members and non-VA researchers interviewed believed that the MVP will enhance collaboration within VA and with the academic affiliates and will ultimately benefit the larger scientific community. These interviewees also pointed out that no other organization in the country was capable of taking on an initiative of this magnitude. University affiliates working on similar smaller-scale initiatives look to VA for best practices. One informant categorized the MVP program as VA's version of the Framingham Heart Study, an ongoing longitudinal study by NIH and Boston University, which identified common factors and causes of cardiovascular disease.

While acknowledging that many of the BLR&D projects will not result in immediate benefits to Veterans, the interview subjects highlighted the importance of this Service to VA research. First, basic research is crucial for understanding the biology of disease and thus for the development of new interventions, and it is not possible to know ahead of time what scientific directions will lead to medically relevant discoveries. In addition, much of basic research at VA focuses on diseases and conditions specific to Veterans, but which may not be prevalent in the general population and thus are of limited interest to other funders. Furthermore, the opportunity to engage in research at VA serves as a tool for recruitment of clinicians, and the program has to accommodate the interests of these individuals, which might be in basic research. Finally, basic research facilitates collaboration between VA and academic medical centers.

Clinical Science Research and Development Service (CSR&D)

The CSR&D Service supports human subject research to determine the feasibility and effectiveness of new treatments and interventions. A sample of topics currently studied under CSR&D includes pharmacotherapies for PTSD, diabetes mellitus, and severe mental illness. We were told that aside from the Cooperative Studies Program, BLR&D and CSR&D are very similar and may even be seen as one

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17 Genomics and proteomics are whole organism studies of genes and proteins.
18 Interview.
19 Informant interview #39, April 4, 2011.
21 www.research.va.gov/programs/csrd/.
Service. For example, many of the BLR&D and CSR&D proposals are evaluated by the same peer review panels.  

The Cooperative Studies Program (CSP) is the multi-site clinical trial arm of VA. ORD investigators work across VA facilities and use the same study protocol, and thus can enroll more subjects. Currently, CSP includes approximately 250 investigators participating in 40 active CSP clinical trials. CSPs are usually multi-site Phase III and Phase IV clinical trials and involve previously approved devices or interventions.

While managed by CSR&D, CSP has a different application process. PIs interested in participating in CSP first submit a letter of intent to ORD. It is reviewed by senior staff at and outside of VA and if the idea is deemed promising, an initial planning process begins. PIs are put in touch with one or more of the coordinating centers (funded by ORD), which include pharmacy, economic research, tissue repository, and other important tools and resources that are accessible to all VA researchers, including a central IRB. The protocol is then evaluated for innovativeness, feasibility, and other traditional peer review criteria. If the proposal achieves a good score in the scientific peer review, the project can begin.

**Health Services Research and Development Service (HSR&D)**

HSR&D supports research on various aspects of health care delivery at VA. This includes the quality of patient care, access to care, health outcomes, and the cost of care. Current special initiatives at HSR&D focus on post-deployment health, with projects focusing on traumatic brain injury (TBI), depression, PTSD, rehabilitation, community reintegration, substance use disorders, and issues unique to women Veterans.

**Rehabilitation Research and Development (RR&D)**

The RR&D Service develops tools and approaches to restore Veterans to full and productive lives. Currently, the key focus of RR&D is on research in the areas of tissue engineering, prosthetics, orthotics, and other assistive devices. In addition, the Service focuses on the restoration of physiologic functions and social integration, including return to employment.

**Cross-ORD programs**

In addition to the four Services, ORD includes several programs that serve the entire research community: the Program for Research Integrity Development and Education (PRIDE), the Center on Advice and Compliance Help (COACH), and the Technology Transfer Program (TTP). PRIDE’s mission is to protect human research subjects by developing policy and guidelines and providing training regarding human subject protection. COACH is a support office of PRIDE that provides regulatory and policy compliance assistance to researchers. Lastly, TTP facilitates translation of VA discoveries into health care tools by commercializing the products resulting from VA research. Exhibit 6 shows the overall organizational chart as well as the reporting relationships of the four Services.

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22 Informant interview #4, April 20, 2011.

23 Data from ORD.


Exhibit 6. ORD organizational chart

Source: Office of Research and Development.

Research centers

In addition to individual awards, the Services also fund Research Centers of Excellence (CoE) and the Research Enhancement Award Program (REAP). Research CoEs are teams of researchers funded to build capacity in particular research area, including investigators, statisticians, economists, and other social scientists to support and facilitate research projects. REAPS are identical to research CoEs, but on a smaller scale.

Center programs are currently undergoing significant changes. BLR&D and CSR&D are terminating research CoEs and REAPs and moving towards a Program Project model, similar to the P01 mechanism at NIH. Program Projects will have three closely related projects and a common core. RR&D has no immediate plans to change research CoE or REAP programs. HSR&D is phasing out both programs within the next 2-3 years and replacing them with two new initiatives: the Collaborative Research to Enhance and Advance Transformation and Excellence (CREATE) initiative and the Centers of Innovation (COIN) program.27

27 www.hsrd.research.va.gov.
The concept for CREATE involves an increased focus on specific outcomes and on an early partnership with the consumers and stakeholders of the research, to facilitate implementation of research findings. The program was described to us as a replacement for research CoEs, but with greater emphasis on partnerships. HSR&D has been introducing the program to the VA leadership and the research community, and plans to launch the program with three to five centers. HSR&D is soliciting applications for the CREATE program.

We understand that the concept of COIN is still under development and that HSR&D leadership is working on the definition and measurement of the impact on Veterans. HSR&D is planning to fund approximately 15 COINs.

Another program managed by HSR&D is the Quality Enhancement Research Initiative (QUERI). QUERI was established approximately 10 years ago, and stemmed from the recognition of the divide between the identification of best treatment options and the uptake of these best practices by the health care system. The goal of QUERI is to identify gaps in the delivery of care to Veterans and to implement corresponding enhancements (which may include new treatments, tests, and models of care). It is an unusual program in the ORD portfolio because it is managed by ORD staff and involves ORD researchers, but it is funded by and is accountable to the clinical care division of VHA. The total funding per QUERI is $570,000 for three years, although funding is contingent on the annual budget.

Currently, there are 10 QUERIs which focus on mental health, heart disease, heart failure, spinal cord injury, drug abuse, and several other diseases and conditions. All QUERI projects go through similar research stages, which were described to us as follows:

- Identify a relatively narrow problem
- Evaluate what outcomes can be changed
- Determine how well the current system works and what are the sources of variation
- Determine how the outcomes can be improved
- Test in a local setting, then in the network, and finally across networks.

The expectation for QUERIs is to identify a problem in a health care setting and help clinicians implement solutions and, according to the interviewee, the program can claim some successes. For example, QUERI developed a collaborative care model that included a connector between psychiatric and primary care. This model is now used at 60 VAMCs. Another important benefit of QUERIs is that they built strong relationships between researchers and health care providers. Finally, QUERIs have amassed knowledge about obstacles to implementation and the best solutions. In the next 5–10 years, the QUERI program leadership is planning to apply principles from systems engineering to improve the effectiveness of health care delivery.

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28 Interview #4. April 2011.
29 Interview #34. April 2011.
External Program Oversight

The research program is overseen by the National Research Advisory Council (NRAC). According to its charter, NRAC provides advice and recommendations to ORD in the following areas:30

- Research-related policies and procedures
- High priority health care needs of Veterans
- Balance of basic, applied, and outcome research
- Scientific merit review process
- Mechanism by which ORD can leverage resources
- Response to changing health care needs
- Protection of human subjects participating in research

NRAC is comprised of 12 VA and non-VA members, who are selected based on their technical expertise. Members are appointed by the Secretary for 2-year terms and the Chair for a 3-year term, with the option of reappointment for additional terms.31 It appears from the interviews that the Council membership has not changed significantly over the last few years. NRAC prepares an annual report for the Secretary containing a comprehensive summary of the work completed during the past year.

Medical Research Staff

To characterize medical research staff, we pieced together data provided to us by ORD with the information collected in the researcher survey. Exhibit 7 shows the number of PIs and research staff for the past six years. The chart shows that the researcher population fluctuated somewhat over the years and has been on the upward trend since 2008.

Exhibit 7. Number of ORD-paid PIs and research staff by fiscal year

Source: ORD.

30 Department of Veterans Affairs Charter of the National Research Advisory Council.
31 Department of Veterans Affairs Charter of the National Research Advisory Council.
ORD also provided us with the number of PIs by VA Service. BLR&D remains the largest VA Service, and RR&D the smallest, while CSR&D and HSR&D are roughly the same in the number of researchers (Exhibit 8). In addition to this core group of researchers, many more individuals have access to VA facilities, resources, or patients. ORD estimates this group at approximately 8,000 persons.

**Exhibit 8. Number of VA-funded researchers by Service**

![Bar chart showing the distribution of VA-funded researchers by Service.](chart)

*Source: Abt Associates survey of researchers and ORD.*

N=2,081.

To be eligible for ORD funding, a VA researcher must be employed at 5/8th Full Time Equivalent (FTE) or more, although in rare cases exceptions to this policy are made. Consistent with this policy, only 2% of survey respondents reported being employed at VA for less than half time and almost 70% were employed full time (Exhibit 9). Distribution of FTEs was similar across Services (Exhibit 9).

**Exhibit 9. Distribution of VA-funded researchers by type of appointment**

![Bar chart showing the distribution of FTEs among VA-funded researchers.](chart)

To be eligible for ORD funding, a VA researcher must be employed at 5/8th Full Time Equivalent (FTE) or more, although in rare cases exceptions to this policy are made. Consistent with this policy, only 2% of survey respondents reported being employed at VA for less than half time and almost 70% were employed full time (Exhibit 9). Distribution of FTEs was similar across Services (Exhibit 9).

32 Conversations with ORD staff.
We also examined the distribution of VA PIs by type of degree. We found that the research community is split roughly half and half between MDs and PhDs; 9% of the researchers had earned both of these degrees and 3% had masters degrees (Exhibit 10). This distribution was consistent with survey responses (data not shown).

**Exhibit 10. Distribution of VA-funded researchers by degree**

<table>
<thead>
<tr>
<th>Service</th>
<th>Type of appointment</th>
<th>&lt;5/8th</th>
<th>5/8th</th>
<th>6/8–7/8th</th>
<th>8/8th</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLRD</td>
<td></td>
<td>2%</td>
<td>23%</td>
<td>9%</td>
<td>65%</td>
<td>1%</td>
</tr>
<tr>
<td>CSRD</td>
<td></td>
<td>5%</td>
<td>14%</td>
<td>11%</td>
<td>69%</td>
<td>1%</td>
</tr>
<tr>
<td>RRD</td>
<td></td>
<td>2%</td>
<td>14%</td>
<td>4%</td>
<td>79%</td>
<td>1%</td>
</tr>
<tr>
<td>HSRD</td>
<td></td>
<td>2%</td>
<td>20%</td>
<td>9%</td>
<td>68%</td>
<td>1%</td>
</tr>
</tbody>
</table>

*Source: Abt Associates survey of researchers.*

N=1,034.

Of 2,152 VA-funded PIs listed in the ORD files, 94% had an academic affiliation (data not shown). This was consistent with the survey data: of 883 respondents, 836 (95%) claimed to have an affiliation (data not shown). VA researchers are affiliated with nearly two hundred institutions across the country, including top research universities in biological sciences, such as Harvard, Yale, UCSF, and Stanford. In Exhibit 11, we present the names of affiliate institutions with 50 or more VA PIs.
VA researchers responding to the survey are well known and recognized by the scientific community, as evidenced by memberships on journal editorial boards (24% of PIs), peer review panels (52% of PIs), and federal advisory councils (10% of PIs). Twelve percent of respondents indicated that they play a leadership role in professional societies. Further, in the exceptionally competitive funding climate, VA researchers were able to obtain over $700 million in extramural support in 2010 (data not shown).

**Exhibit 11. Distribution of VA PIs by affiliate university**

<table>
<thead>
<tr>
<th>University</th>
<th>Number of researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA</td>
<td>78</td>
</tr>
<tr>
<td>UCSD</td>
<td>68</td>
</tr>
<tr>
<td>University of Washington</td>
<td>65</td>
</tr>
<tr>
<td>UCSF</td>
<td>63</td>
</tr>
<tr>
<td>Oregon Health &amp; Science University</td>
<td>62</td>
</tr>
<tr>
<td>Stanford University</td>
<td>58</td>
</tr>
<tr>
<td>University of Iowa</td>
<td>56</td>
</tr>
<tr>
<td>University of Michigan</td>
<td>53</td>
</tr>
<tr>
<td>University of Pittsburgh</td>
<td>51</td>
</tr>
</tbody>
</table>

*Source: ORD.*

Only institutions with 50 or more PIs are shown. N=2,041.

We also examined the distribution of the researchers by academic titles. As Exhibit 12 shows, 805 (37%) were full professors, 528 (25%) associate professors, and 670 (26%) assistant professors.

**Exhibit 12. Distribution of VA-funded researchers by academic title**

<table>
<thead>
<tr>
<th>Academic Title</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor</td>
<td>805</td>
</tr>
<tr>
<td>Associate Professor</td>
<td>528</td>
</tr>
<tr>
<td>Assistant Professor</td>
<td>570</td>
</tr>
<tr>
<td>Instructor</td>
<td>43</td>
</tr>
</tbody>
</table>

*Source: ORD.*

N=2,152.
Exhibit 13 presents the composition of the research community by specialty. Of 2,152 researchers, over a quarter were internists and 15% psychologists and psychiatrists. Also in the top six were neurologists (5%), biochemists (4%), and surgeons (3%). Note that an additional number of researchers were identified as biologists, cell biologists, molecular biologists, and geneticists, and could probably be grouped with biochemists into larger biology group. We decided against making arbitrary groupings in favor of presenting the data as they were provided by ORD.

**Exhibit 13. Distribution of VA-funded researchers by specialty**

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Number of Researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Medicine</td>
<td>571</td>
</tr>
<tr>
<td>Psychology</td>
<td>199</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>126</td>
</tr>
<tr>
<td>Neurology</td>
<td>117</td>
</tr>
<tr>
<td>Biochemistry</td>
<td>80</td>
</tr>
<tr>
<td>General Surgery</td>
<td>68</td>
</tr>
</tbody>
</table>

*Source: ORD.*

N=2,152. Only categories with 50 or more researchers are shown.

As researcher gender and age were not available from ORD, we collected these data in the survey. We found that a third of survey respondents willing to indicate their gender were women and 62% were men (Exhibit 14). We do not know whether this distribution is representative of the community. The survey of researchers conducted in 2000 reported that 24% were women (data shown in RI-5).

**Exhibit 14. Distribution of VA-funded researchers by gender**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Percent Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>33</td>
</tr>
<tr>
<td>Male</td>
<td>62</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>5</td>
</tr>
</tbody>
</table>

*Source: Abt Associates researcher survey.*

N=1,034.
Like gender, data on researcher age are not collected by ORD and we asked this question in the survey. Age distribution is shown in Exhibit 15 and indicates that the research community is skewed toward individuals in mid- to late careers as 71% of respondents were over the age of 45. Half of respondents spent 11 years or more at VA.

**Exhibit 15. Distribution of VA-funded researchers by age and duration of service**

![Age distribution chart]

Source: Abt Associates researcher survey.
N=1,034.

**Non-Profit Corporations**

The enactment of Public Law 100-322, the Veterans Benefits and Services Act of 1988, allowed VA to establish non-profit research corporations (NPCs). NPCs made it possible for VA researchers to obtain funds from extramural sources, in particular from NIH. The main function of the non-profits is to manage funds from non-VA sources including industry sponsors and entities such as NIH. In addition, NPCs support VA in other ways. For instance, some NPCs provide funding to newly hired investigators (“start-up” funds) and to investigators who have temporarily lost funding support (“bridge” funds). These types of funding are common at universities, but are not available at VA.
NPCs are eligible to receive administrative indirect costs from NIH grants that they manage. They are not eligible to receive the facilities portion of NIH indirect costs for research taking place within VA facilities, but can receive them if research is taking place in a building owned by the NPC. For instance, a laptop purchased by the university with an NIH grant can be donated to VA via a non-profit. Moreover, 100% of NPC-administered grants are considered in the VERA calculation versus 75% for university-administered grants (VEAR calculations are described below). VERA is a methodology used by ORD to calculate the amount of funding allocated to VAMCs. The higher the total grant funding received by a facility, the larger its VERA share will be.

As is discussed later in this report, 67% of ORD-funded researchers surveyed indicated that it took HR longer than four month to hire personnel into their research groups (for 10% of researchers it took longer than a year). An important benefit of the non-profits and affiliates is that they provide a mechanism to bypass these delays by using the Interagency Personnel Agreement (IPA). At present, to be eligible for an IPA the individual being hired must be an employee of the NPC or of the affiliate for three months and every four years the IPA must be suspended for an interval. At some sites this interval is interpreted as needing to be 61 days in length; in other sites, it has been interpreted as needing to be one year. According to the interviewees, VA may decide to enforce the 1-year hiatus. This change in policy will have significant negative consequences for the progress of research, as the short duration of ORD-funded projects does not permit long hiring delays and the research community uses IPAs as a mechanism to quickly bring in the expertise that they need for the project.

Despite the obvious advantages to VA in using non-profits to apply for extramural grants, many PIs choose to go through their university. Two reasons were given for this decision: some researchers feel greater loyalty to their university than to VA, and their advancement on the academic ladder depends on the amount of funding that they bring to the university. NIH grants administered through the non-profit also do not count towards the university’s ranking for NIH funding.

From the interviews with ACOS, it appears that VAMCs differ in their policies for applying for extramural funding. In some cases, all PIs apply through either the university or the non-profit, and in other cases it is a mix of the two. One ACOS said at their facility the application is made through the NPC if most of the PI's research support is through the VA, and through the academic affiliate if most of the support is through the university. There seems to be an understanding between a VAMC and an affiliate how grant applications are handled. According to the 2009 Non Profit Corporation report, approximately 20% of all VA extramural research dollars, or $240 million, were administered by NPCs.

VA has 86 NPCs distributed across the country. In most cases one non-profit supports one VAMC, but facilities with smaller research programs share non-profits. An informant knowledgeable about NPCs told us that only VAMCs with robust research programs can support a non-profit.
Chapter 4: Research Funding and Partnerships

VA researchers receive support from several sources. Relative funding amounts by source and by research area, as well as processes for allocating these resources to the research community, are discussed in this chapter. Also examined are academic and industry partnerships and their role in the VA research enterprise.

Research Funding

We obtained from ORD and analyzed funding data for the past six years. Support for VA research comes from several principal sources: research appropriations, the VERA system which allocates funds appropriated for Veterans' medical services and facilities, other federal agencies, and non-federal entities (Exhibit 16). As the chart shows, research appropriation funds continued to increase in the past six years, at 8% on average, to reach an estimated $581 million in FY2010. VERA support almost doubled over the period examined. In contrast, funding from federal sources has declined and funding from non-federal sources remained flat.

Exhibit 16. Budget history

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research appropriation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal resources</td>
<td>10%</td>
<td>-2%</td>
<td>-17</td>
<td>-7</td>
<td>5%</td>
</tr>
<tr>
<td>Other non-federal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>resources</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VERA research support</td>
<td>5</td>
<td>4%</td>
<td>9</td>
<td>7%</td>
<td>5</td>
</tr>
</tbody>
</table>

Source: Office of Research and Development.
VERA research support

The VERA system is a method used by VA to allocate appropriated funds to VAMCs. Originally developed to correct for shifts in Veteran population from the northeast to the south and from the midwest to the west, the methodology was adopted by VHA to allocate resources to the field in an equitable manner. VERA allocation for research is intended to cover the expenses of administering research, including the salaries of clinicians paid by the medical center while conducting research. In addition to salaries, VERA funds cover administration and repairs. The funds are distributed to the VISNs which in turn allocate them to the individual VAMCs.

The VERA amount is calculated based on prior funding amounts, from both VA and non-VA sources (Exhibit 17). The funding amounts are weighted based on the source as follows: (a) VA grants and NPC-administered grants are fully weighted and (b) university-administered and industry funding is discounted by 25% and 75%, respectively. The weighted sums from all of the medical centers are added together and divided by the amount of VERA research dollars available in that year. The available VERA dollars are the same amount as the research appropriation requested in the President’s budget for that year. The ratio between the national total of weighted research expenditures and the amount of available VERA Research dollars is the National Price for Research Support. Each VAMC is then allocated the product of their total research expenditures times the national price for research support. Below is an example of how VERA dollars are calculated.33

Exhibit 17. VERA funding calculations

<table>
<thead>
<tr>
<th>Source: Abt Associates.</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA grant: ( $150,000 \times 100% = $150,000 )</td>
</tr>
<tr>
<td>NIH grant (through NPC): ( $250,000 \times 75% = $187,500 )</td>
</tr>
<tr>
<td>Industry: ( $100,000 \times 25% = $25,000 )</td>
</tr>
<tr>
<td>Total: ( $362,500 )</td>
</tr>
<tr>
<td>National Price for Research Support ( \times $0.56 )</td>
</tr>
<tr>
<td>VERA funding ( $362,500 \times $0.56 = $203,000 )</td>
</tr>
</tbody>
</table>

Funding mechanisms

VA researchers obtain funding for proposed investigations via several mechanisms. By far the most common type of funding is through investigator-initiated proposals (Exhibit 18). These are funds awarded to individual investigators and are analogous to R01s at NIH. Over the course of the past six years, ORD funded between 1,600 and 1,800 grants each year at a cost of approximately $300–400 million per year.

The next two largest investments were in the research Centers of Excellence (CoEs) and the Career Development Awards. For these programs, the funding amounts have increased from approximately

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33 ORD Lecture to Chief of Staff and Medical Center Directors.
$45 million to $65 million. According to ORD data, expenditures on service-directed programs (studies conducted in response to directions from the Congress or the Secretary\(^{34}\)) peaked in 2006 at $30 million, then went down to $2 million for the next two years and reached a new high in FY10 at $63 million.\(^{35}\)

**Exhibit 18. Funding and number of projects by activity, in $ thousands**

<table>
<thead>
<tr>
<th>In $ thousands</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator-initiated</td>
<td>$297,943</td>
<td>$209,475</td>
<td>$266,157</td>
<td>$364,919</td>
<td>$358,474</td>
<td>$340,366</td>
</tr>
<tr>
<td>Career development</td>
<td>$43,902</td>
<td>$57,131</td>
<td>$53,841</td>
<td>$56,356</td>
<td>$44,761</td>
<td>$63,160</td>
</tr>
<tr>
<td>Special research initiatives</td>
<td>$18,093</td>
<td>$0</td>
<td>$6,347</td>
<td>$5,631</td>
<td>$5,744</td>
<td>$0</td>
</tr>
<tr>
<td>Centers of Excellence</td>
<td>$46,403</td>
<td>$49,338</td>
<td>$45,758</td>
<td>$47,613</td>
<td>$55,470</td>
<td>$65,988</td>
</tr>
<tr>
<td>Service-directed research</td>
<td>$6,358</td>
<td>$30,671</td>
<td>$2,137</td>
<td>$1,965</td>
<td>$6,136</td>
<td>$40,570</td>
</tr>
</tbody>
</table>

*Source: Office of Research and Development.*

Each funding mechanism has a maximum allowable annual amount; these limits vary by Service. For example, an upper limit for an investigator-initiated study at BSR&D and CSR&D is $150,000 and at RR&D and HSR&D is $300,000 per year (data not shown).

We found no evidence of a specific process or mechanism for funding long-term and large-scale projects. Most often, the duration of the project is extended via competitive renewals. However, on

\(^34\) VA OR Excellence Through Research Report.

\(^{35}\) ORD Finance.
occasion ORD does fund large-scale projects. For instance, the recently launched Million Veterans Project is a significant investment, which will continue for at least the next 5–7 years. 36

**Setting of Research Priorities and Portfolio Management**

A number of factors influence the direction of VA research. First, the program is driven by its mission of addressing the diseases and conditions affecting Veterans. In addition, ORD continuously receives input from Congress and VSOs, who are advocating for more research on specific diseases and conditions. Further, ORD must maintain scientific diversity, so that the community can respond to the changing scientific landscape and Veterans’ needs. The program is an important tool for recruitment and retention of clinicians, and thus the research portfolio is shaped by the interests of these clinicians (and of other researchers at VA). Finally, the program is affected by changing scientific opportunities and gaps in current knowledge.

ORD leadership has several tools to steer the program. CRADO, Deputy CRADOs, and the Service Directors interact with Congress, VSOs, other funders, and universities to identify the interests and needs of these communities. Based on this input, ORD formulates research priorities, which are communicated to the research community. For example, the HSR&D web site highlights its current focus in the areas of health care access and health disparities, health care informatics, long-term care, mental and behavioral health, and women’s health.37 While VA research projects are mostly investigator-initiated, these priority announcements signal to the researchers what proposals will be of special interest, and consequently more likely to be funded. Several informants stated that researchers are very adept at receiving and responding to these cues. Research grants are limited in duration with a possibility of renewal, and ORD retains the ability to terminate unproductive projects and to nurture promising research.

Another tool for shaping VA research is program announcements (PAs) and requests for application (RFAs), which are issued by ORD to support research in a specific area, often related to deployment health. For example, homelessness among Veterans is a big issue for the Secretary of VA and the President. In response, ORD released an RFA for research on homelessness, developed in collaboration with the Office of Homeless Programs, which helped identify key research topics that could be addressed. 38

ORD can build capacity in a particular area by advertising for and supporting research centers. These centers are funded at higher levels and for longer time than individual awards and thus can nucleate a team around a research problem. Other federal funders, for example NIH and the Agency for Healthcare Research and Quality (AHRQ), use centers in a similar manner to promote interdisciplinary and/or team science.

All research at VA undergoes peer review.39 The details of this process are described elsewhere in this report, but for the purposes of this discussion it is important to note that peer review is a powerful force shaping the program. The idea behind peer review is to subject research proposals to the scrutiny of experts in the research area being proposed, so that scarce resources can be directed to the best

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36 Key informant interview. We do not have data on the level of funding for this Million Veterans Project.


38 Interview #4, December 17, 2010.

39 Key informant interview.
research proposals. While ORD communicates to the reviewers that a certain research direction is a priority for VA, the most important factors in the acceptance or rejection of a proposal are its technical quality and feasibility.

Finally, as VA research funds are relatively limited, intramural funding is to some extent seen by the leadership as seed money, which should be leveraged with other federal and industry funding. Therefore, research priorities of other funders – most notably NIH – also shape the direction of the VA program, as the research community is influenced by the directions established by NIH. (One interviewee called leveraged funding a “perverse incentive” because VA is supposed to sponsor research that is distinct from NIH.)

The process of funding allocations is monitored by the National Research Advisory Council (NRAC), which is responsible for ensuring that VA maintains its focus on Veterans’ needs and yet supports a balanced portfolio of basic, applied, rehabilitation, and outcomes research. NRAC members saw ORD as successful in being able to steer and balance the program. Exhibit 19 is a summary of how the research portfolio is established and what forces influence its direction.

Exhibit 19. The process of priority setting and funding allocation

Source: Abt Associates.

40 Key informant interviews.
Procedures for funding extensions and renewals

According to ORD staff, there is a formal process for receiving a project extension. An investigator will usually work with the facility’s Associate Chief of Staff for Research (ACOS) and the medical center director to draft a letter to the director of the funding Service. The letter will highlight reasons for the extension request, the duration requested, and whether the extension will include funding from the local facility. The majority of extension requests receive no-cost extensions. Researchers can also obtain funded extensions, typically for about six months, from their facility, university affiliate, or nonprofit research corporations. In addition, researchers may request renewal of funding up to one year prior to the end of their funding as long as the RFA is still active.

Researchers are eligible to apply for additional funding under an existing merit review process, if the applicable RFA/PA is still active and if their current award expires within one year. This allows researchers to submit their proposals one review cycle ahead of the end date of their active project. Unsuccessful applications will receive feedback from the review panel and will have an opportunity for another application attempt before their award ends. This process was put in place to avoid interruptions in funding.

Funding for equipment and materials

VHA Handbook 1202.06 entitled Research Equipment Management Program defines procedures for management, procurement and disposition of research laboratory and laboratory animal management equipment purchased with VA appropriated dollars. Processes for managing research equipment include Shared Equipment Evaluation Program (ShEEP), Laboratory Animal Management (LAMb) program, and Research Equipment Quick Initiative Program (REQUIP). ShEEP is a process for procuring common or shared equipment; this equipment may be shared within VA or between VA and the academic affiliates. LAMb is used to fund equipment to handle laboratory animals. Through ShEEP and LAMb, a facility may request five pieces of equipment annually with a combined total of $250,000.

REQUIP supports the reassignment of usable research equipment between VA facilities. If research equipment has been deemed no longer useful, including through REQUIP, it must be disposed of appropriately following VHA guidelines.

The outcome of the equipment funding request depends on the answers to the following questions: Does the equipment fall within the scope of the program? Is the sharing cost sufficient to purchase the equipment? Is the equipment well justified? Is it a necessary to conducting research? Are the investigators who will share the piece of equipment productive members of the research community? What is the status of the local research facility? Does it have a viable future? Is the local facility capable of housing and maintaining the equipment?

Research material and supplies are purchased using the traditional procurement process. Orders are handled by the purchasing agent using the same process as for other medical center supplies. Some of the ACOS interviewed reported that purchasing agents do not understand research needs. For instance, the agents challenge the investigators who want to purchase costly laboratory reagent from a particular

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41 Interview #54, May 31, 2011.
42 VHA Handbook 1202.01.
43 VHA Handbook 1202.06 Research Equipment Management Program.
vendor. We were also told that purchasing staff do not understand that biological products may require special handling or have a limited shelf life. The problem is especially acute when researchers are initiating a new project. Procurement rules may require sole source justification, which delays acquisition of supplies and equipment and holds up the start of a project. One ACOS noted that "one size fits all" government rules prevent investigators from efficiently using the research funds they receive.

**Funding for high priority areas**

The Veterans Health Administration serves Veteran populations with different health care needs. Some Veterans require treatment for conditions associated with aging, such as cancer, degenerative diseases, and cardiovascular diseases, while others returning from current conflicts may require care for war wounds. Exhibit 20 illustrates that ORD aims to maintain a balance between deployment-related research and research on the diseases associated with aging Veterans.

According to the NRAC report, one of ORD’s goals is to understand, prevent, and treat PTSD. In FY2010, ORD funded over 100 PTSD projects at a cost of more than $25 million. Specific studies funded include the analysis of this condition across deployments and the evaluation of the feasibility of PTSD treatment using the drug called Risperidone, which is often used in persons suffering from unusual thinking or depression.\(^{44}\)

With a large number of amputations and blast injuries from the current conflicts, VA has a strong focus on research on traditional and neural prosthetics. Osseointegration, which allows for direct attachment of prosthesis eliminating sockets, a powered prosthetic ankle, and the DEKA prosthetic arm are examples of recent VA-sponsored research in this area.\(^ {45}\) In FY2010, ORD spent $13 million or 2% of its total budget on prosthetics and amputation care research (Exhibit 20).

Gulf War Veterans (Veterans with service in Kuwait and Iraq in the 1990s) continue to exhibit symptoms and health conditions that cannot be explained by routine medical diagnoses. In 1995 and 1996, the Persian Gulf Veterans Coordinating Board published a report that contained 21 epidemiological questions aimed at determining whether Gulf War Veterans experience a greater prevalence of specific symptoms.\(^ {46}\) In 2004, these questions were transformed into research topics and VA developed short-term and long-term plans to tackle the problem. In the short term, VA plans to identify potential treatments and new diagnostic markers of disease; the long-term plan is to design and implement group studies of Gulf War Veterans, including a genome-wide association study. Currently, VA spends $23 million or 4% of its budget on Gulf War Veterans’ illnesses (Exhibit 20).

As more women join the service, ORD has become increasingly committed to research focused on women’s issues. Specifically, VA is conducting studies on the quality of care delivered to women, sexual and other traumas, reintegration and readjustment post-deployment, and the relationship between gender and access to care for PTSD. In FY2010, VA expenditures on women’s health research were $11 million or 2% of the budget (Exhibit 20).


\(^{45}\) Ibid.

\(^{46}\) NRAC Report 2010.
For FY2012, ORD will continue to place high priority on research projects which focus on serving the need of Veterans returning from wars in Iraq and Afghanistan. In addition, ORD plans to maintain support for research on Veteran homelessness, mental health, Gulf War Veterans' illness and exposure, prosthetics, traumatic brain injury, spinal cord injury, and others research topics which affect different Veteran cohorts.

### Exhibit 20. Funding by high priority areas

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of funded projects</th>
<th>Total FY2010 funding*</th>
<th>% of research budget†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deployment-related research</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traumatic brain injury</td>
<td>98</td>
<td>$22,167,692</td>
<td>3.8%</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>130</td>
<td>$29,880,771</td>
<td>5.1%</td>
</tr>
<tr>
<td>Sensory loss</td>
<td>106</td>
<td>$23,110,891</td>
<td>4.0%</td>
</tr>
<tr>
<td>Post-deployment mental health research</td>
<td>184</td>
<td>$44,639,950</td>
<td>7.7%</td>
</tr>
<tr>
<td>Prosthetics and amputation health care</td>
<td>51</td>
<td>$13,058,771</td>
<td>2.2%</td>
</tr>
<tr>
<td>Pain research</td>
<td>57</td>
<td>$11,040,029</td>
<td>1.9%</td>
</tr>
<tr>
<td>Smoking and other substance abuse disorders</td>
<td>125</td>
<td>$21,798,236</td>
<td>3.8%</td>
</tr>
<tr>
<td>Gulf War Veterans’ illnesses research including infectious diseases of Persian Gulf</td>
<td>54</td>
<td>$23,250,066</td>
<td>4.0%</td>
</tr>
<tr>
<td>Women Veterans' health issues</td>
<td>50</td>
<td>$12,636,207</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Research on Diseases of Aging</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aging and geriatric research (general)</td>
<td>500</td>
<td>$92,155,064</td>
<td>15.9%</td>
</tr>
<tr>
<td>Alzheimer’s disease and other dementias</td>
<td>110</td>
<td>$22,807,854</td>
<td>3.9%</td>
</tr>
<tr>
<td>Cardiovascular disease and stroke</td>
<td>305</td>
<td>$55,336,338</td>
<td>9.5%</td>
</tr>
<tr>
<td>Prostate cancer and benign prostatic hyperplasia (BPH)</td>
<td>45</td>
<td>$12,214,973</td>
<td>2.1%</td>
</tr>
</tbody>
</table>


*Includes indirect costs.

†The percentages could increase or decrease depending on how the areas are defined.

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Relationship between funded research and health care costs

In order to understand the relationship between funded research and health care costs, VA requested analysis of research funding by the codes used for clinical diagnosis, such as Diagnosis-related Group (DRG) or International Classification of Diseases-9th revision (ICD-9) codes. However, as these codes were not designed for this purpose, an analysis of this type would have a number of limitations. First, some of the codes lack the necessary level of specificity. For instance, an ICD-9 code “general symptoms” will not be useful for a research categorization. In addition, there are no ICD-9 codes that would map onto much of health services research, because the focus of this research is health care delivery and not specific diagnoses.

However, understanding the relationship between research and health care expenditures is important. The study performed by the Office of Inspector General in 2009, Review of the Veterans Health Administration's Use of Appropriated Funds for Research, was one attempt at answering this question.48

The authors enumerated the number of ORD studies and funding levels by Designated Research Areas (DRA) codes, and then compared these data to the most common conditions for which Veterans seek care at VA using frequent discharge diagnoses, including mental illness, substance abuse, and diseases associated with aging. The study concluded that the distribution of funds for research at VA was appropriate for the population of Veterans treated, although it pointed out that reporting on funding expenditures could be more transparent.

For this evaluation, ORD staff performed an additional analysis of the relationship between research emphasis and the illnesses and diseases from which Veterans are most likely to suffer. Exhibit 21 displays the correlation between VA research expenditures for particular DRAs and the annual cost of these conditions to VA calculated based on ICD-9 codes. Two trends emerge from the chart. First, the conditions that account for a substantial portion of VA health care costs – mental health and cardiovascular disease – are proportionally represented in the research portfolio. In addition, research expenditures are consistent with the program mission to serve the special needs of Veterans, as conditions that affect a small total number of Veterans, such as TBI and spinal cord injury, are high priority areas for ORD and thus receive significant funds.

48 Office of Inspector General (OIG), Review of the Veterans Health Administration's Use of Appropriated Funds for Research.
Exhibit 21. Relationship between health care and research expenditures

Source: Office of Research and Development.

The exhibit represents 61% of the VA research portfolio. Only the top 40 most costly or most frequent ICD-9 codes were considered. Some ICD-9 codes do not map to any particular DRA category and were not included. Some DRAs (for example, aging) do not correlate with unique and/or specific ICD-9 codes and others are not associated with particular ICD-9 codes (for example, health systems).

Funding priorities of the research community

In the survey, research leadership – ACOS and center directors – were asked to indicate their top funding priorities if funding were increased by 10% and 25%. For consistency, respondents were offered the same choices:

- Career development programs
- Investigator-initiated projects (e.g., merit reviews)
- Multi-site studies (CSP)
- Pilot studies
- Research Centers of Excellence
- Research equipment
- Research office staff
- Research facilities.
Survey data are presented in Exhibit 22. It shows that funding for merit awards was high priority for the largest percentage of respondents in both groups: 78% of research CoE/REAP directors and 70% of ACOS. This was followed by funding for career development program, selected by roughly a third of respondents in both groups. The two groups were also in agreement about support for research office staff, which was selected as a top priority by 21% of ACOS and 15% of center directors. Funding for research equipment was of least importance to both groups. According to survey data, CoE/REAP directors were much more in favor of funding research centers than ACOS: 42% of the directors indicated that this was a priority versus only 1% of ACOS. ACOS were more interested in supporting pilot studies than center directors (33% versus 15%).

### Exhibit 22. Funding priorities for ACOS and research center directors

<table>
<thead>
<tr>
<th>Priority</th>
<th>ACOS</th>
<th>REAP/CoE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research facilities</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Research office staff</td>
<td>21</td>
<td>15</td>
</tr>
<tr>
<td>Research equipment</td>
<td>42</td>
<td>2</td>
</tr>
<tr>
<td>Research centers of excellence</td>
<td>70</td>
<td>81</td>
</tr>
<tr>
<td>Pilot studies</td>
<td>33</td>
<td>15</td>
</tr>
<tr>
<td>Multi-site studies</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Merit awards</td>
<td>70</td>
<td>81</td>
</tr>
<tr>
<td>Career development programs</td>
<td>29</td>
<td>39</td>
</tr>
</tbody>
</table>

Source: Survey of VA Researchers.

**N_{ACOS}=86; N_{REAP/CoE}=41.**

Based on the priorities expressed by respondents, additional funding can be used in the following way:

- If funding levels were to increase by 10% ($50 million based on projected appropriation for FY2012): increase either the number of merit awards or the level of funding for merit awards, or both. For instance, $50 million can “buy” approximately 45 4-year RR&D merit grants.

- If funding levels were to increase by 25% ($125 million based on projected appropriation for FY2012): increase the number of merit awards and career development awards and provide partial or full support to hire office staff.

In the survey, we asked the research community (VA-funded PIs, ACOS, CSP investigators, and Center directors) several questions to gauge the level of satisfaction with ORD funding process. Respondents overwhelmingly felt that ORD funding focuses on the needs of Veterans (81%, Exhibit 23). However,

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49 Data as of July 8, 2011.
only 35% indicated that the balance among basic, clinical, rehabilitation, and health services research was appropriate. In addition, only 21% agreed or strongly agreed that the level of ORD funding was adequate and only 45% that the duration of funding was adequate.

Exhibit 23. Views on ORD funding

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree/agree</th>
<th>Neutral</th>
<th>Strongly disagree/disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance between basic, clinical, health services, and rehabilitation research is appropriate</td>
<td>35</td>
<td>36</td>
<td>28</td>
</tr>
<tr>
<td>The duration of ORD-funded projects is adequate</td>
<td>45</td>
<td></td>
<td>21</td>
</tr>
<tr>
<td>ORD funding levels for research are adequate</td>
<td>35</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td>ORD research funding focuses on the needs of the Veterans</td>
<td>81</td>
<td>16</td>
<td>3</td>
</tr>
</tbody>
</table>

Source: ORD.
N=1,034.

Research Partnerships

Because of its focus on servicemen, VA has historic ties to the Department of Defense (DoD). These ties extend to research-related activities. VA and DoD have a joint research mission. A special body, the Health Executive Council (HEC), was created to coordinate health care initiatives and programs under the two Departments' Joint Executive Council. VA and DoD personnel serve on each other’s peer review panels and DoD staff serve on NRAC.

Our findings from the key informant interviews suggest that the relationship between the two agencies has grown in the past few years, in particular in mental health research (there are 500 research projects in this area in the combined VA-DoD portfolios). We also found that DOD and VA are actively working together to keep each other informed about ongoing research projects and way to coordinate between the two agencies. ORD leadership expressed a keen interest in potential research projects that would link pre-deployment health status to post-deployment health outcomes, since the former inevitably influences the latter. As DoD collects pre-deployment data and VA provides care to Veterans, each

50 VA/DoD Research Collaboration Guidebook.
agency “owns” half of the information. Merging these two sources of data holds great promise for understanding and possibly predicting the impacts of deployment-related injuries, such as TBI or PTSD.

Despite these efforts, interviewees mentioned some challenges to a productive relationship between the two agencies. First, VA and DoD maintain separate health care records, and mechanisms to share this information are still under development. In addition, DoD views any information, including research program information, as confidential such that release of the information could potentially jeopardize national security. For example, there is no publicly accessible complete list of the projects that DoD supports. This is in contrast to NIH, which lists the descriptions of all funded projects and PI names in its open-access Reporter database, and more recently to VA. Another challenge to collaboration is unexpected deployments of DoD personnel that can interfere with the progress of joint VA-DoD research. Navigating different institutional review boards and moving funds between the agencies can also be difficult.

To help researchers interested in collaboration overcome these barriers, VA and DoD developed a document entitled *VA/DoD Collaboration Guidebook for Healthcare Research*. The purpose of this guidebook is to provide researchers with information that they will need to establish cross-agency collaboration. It includes brief reviews of VA and DoD organizational structures, funding mechanisms, research-related policies and procedures, and potential challenges to collaboration. In our view, this guidebook is exceptionally informative and well organized and should be very helpful to researchers both at DoD and at VA who are interested in joint projects.

In addition to DoD, VA has strong ties to NIH, which is the biggest extramural funder of VA research. The relationship between VA and NIH extends beyond funding support, however. For instance, the ORD CRADO serves on the Advisory Board for the National Center for Research Resources. ORD staff frequently meets with program managers at the National Institute of Mental Health, the National Institute on Aging, and the National Institute of Neurological Disorders and Stroke. VA and NIH co-sponsor conferences on various research topics and co-issue Requests for Applications (RFAs). These RFAs include diseases and conditions of mutual interest, including PTSD, TBI, and substance abuse. In preparation for the Million Veterans Program initiative, VA partnered with the National Human Genome Research Institute at NIH to understand Veterans’ knowledge of and attitude toward genomic medicine.

VA recently started using eRA Commons, an NIH-sponsored electronic grants management system used to post and exchange grant-related information between the agency and the researcher community. As noted, starting in 2009 ORD-funded projects are included in the NIH public database Reporter.

VA collaborates with pharmaceutical and biotech companies on clinical trials. To examine the level of industry partnership, a search of clinicaltrials.gov database using the query “Veterans” was conducted. The search yielded 3040 hits (note that these data maybe underreported for early years); of these, 897

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51 Interview# 22, March 14, 2011.
52 This NIH Center is proposed to be dissolved.
53 Key informant interview #48, April 28, 2011.
54 era.nih.gov/commons/.
56 The search was performed on August 22, 2011.
were studies in progress at the time of the search (data not shown). This result was then limited to the trials that are funded by industry, which returned 563 hits (data not shown). Exhibit 24 shows the distribution of clinical trials by location.

**Exhibit 24. Locations and numbers of clinical trials funded by industry**

![Exhibit 24. Locations and numbers of clinical trials funded by industry](image)

Source: Clinicaltrials.gov. Search performed on August 21, 2011.

We found that VA studies are funded by some of the best known pharmaceutical companies, such as Bristol-Myers Squibb, Merck, Pfizer, and Novartis (Exhibit 25). The largest number of trials target viral diseases (including HIV), vascular disease, and digestive tract disease. Further, the search revealed that 55 studies are Phase IV clinical trials; of these, 24 were marked as “completed.” We examined three random studies: (1) the treatment of PTSD using paroxetine augmented with quetiapine (#NCT00292370, collaboration with AstraZeneca); (2) a comparison between the cost-effectiveness of olanzapine versus haloperidol for the treatment of schizophrenia (#NCT00007774, collaboration with Eli Lilly); and (3) studies of treatment effects of antidepressant paroxetine on platelet calcium in hypertensive and depressed patients (#NCT00018759, collaboration with SmithKline Beecham).
Exhibit 25. Most common industry partners and target conditions

<table>
<thead>
<tr>
<th>Funder</th>
<th>Number of studies</th>
<th>Disease category</th>
<th>Number of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bristol-Myers Squibb</td>
<td>17</td>
<td>Viral diseases</td>
<td>32</td>
</tr>
<tr>
<td>Pfizer</td>
<td>13</td>
<td>Vascular disease</td>
<td>31</td>
</tr>
<tr>
<td>Abbott</td>
<td>10</td>
<td>Digestive system diseases</td>
<td>31</td>
</tr>
<tr>
<td>Sanofi-Aventis</td>
<td>10</td>
<td>Recurrence *</td>
<td>30</td>
</tr>
<tr>
<td>Novartis</td>
<td>8</td>
<td>Carcinoma</td>
<td>29</td>
</tr>
<tr>
<td>Merck</td>
<td>7</td>
<td>Mental disorders</td>
<td>29</td>
</tr>
<tr>
<td>Glaxo</td>
<td>7</td>
<td>RNA virus infections</td>
<td>28</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>5</td>
<td>Heart diseases</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respiratory tract disease</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Male genital disease</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acquired immunodeficiency</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HIV infections</td>
<td>20</td>
</tr>
</tbody>
</table>

*Unspecified disease.

Research opportunities at VA would be significantly reduced without partnerships with universities (which are called “academic affiliates” at VA) and other federal agencies. The benefits of academic relationships are numerous and include access to other federal funding sources, students and peers; use of libraries and equipment; and the prestige of university appointment. Affiliates also provide the cross-fertilization of ideas necessary to conduct cutting-edge research. Finally, VA can engage leading clinicians, who are usually based at medical schools, in the delivery of health care to Veterans.

Universities also benefit from partnering with VA. In conversations with senior academic administrators (deans, department chairs, and vice-chancellors), we learned that VA offers medical students training opportunities at VA hospitals. In addition, by collaborating with VA, university faculty members get access to unique patient populations, such as Veterans with PTSD. VA also contributes to faculty salary, which allows universities to offer more competitive hiring packages (VA also benefits from this arrangement). And finally, VA is a source of intramural funding, which generally has a higher payline than NIH.

In 2010, $710 million dollars, or 38% of total funding for that year, came from outside of VA (Exhibit 26). While the precise effect of industry and academic funding on the completion and dissemination of research results could not be established, given the amount of funding from these sources it is clear that it is instrumental to all aspects of research projects. Survey data supports this conclusion. In the survey, researchers were requested to list three of their most important publications and to indicate whether
these publications were supported in part or in full by VA. Of more than 2055 publications reported, 497 or 24% did not receive any funding from VA. This finding provides additional evidence that outside organizations play a key role in the success of VA research enterprise.\footnote{Data as of July 21, 2011.}

**Exhibit 26. Research funding from non-VA sources**

\begin{center}
\includegraphics[width=\textwidth]{Exhibit26.png}
\end{center}

\textit{Source: Office of Research and Development.}

Relationships between VA and industry are governed by Cooperative Research and Development Agreements (CRADAs). Established under the Federal Technology Transfer act of 1986, CRADAs allow VA to accept personnel, services, facilities, and other resources.\footnote{VHA Directive 2007–044.} The number of CRADAs reflects the scope of the relationship of VA with industry and universities. Based on the data provided by the ORD Technology Transfer office, the number of CRADAs increased from 1 in FY2000 to 897 in FY2010 (Exhibit 27). However, the amount of industry funding decreased from $194 million in FY2005 to $184 million in FY2010 (data not shown).
Virtually all VA researchers have academic appointments at local universities ("academic affiliates" in VA terminology). Many interviewees believed that the benefits of VA-university collaboration are numerous and mutual. VA researchers use their academic appointments to gain access to other researchers, students, and university resources. And finally, VA researchers benefit from the prestige of academic titles.
Chapter 5: Infrastructure for Research

Contemporary biomedical research is a complex enterprise requiring extensive supportive infrastructure. In addition to the facilities where the research is performed, a researcher needs access to equipment and supplies. Furthermore, researchers must obey various laws and regulations to ensure the safety of the study subjects and other researchers. Inevitably, this gives rise to tensions between safety and excessive regulatory burden. In this chapter we examine various aspects of the VA research infrastructure with the focus on the research community’s satisfaction with the research supports.

Research Facilities

According to VA data, there are 109 VAMCs across the country. Exhibit 28 shows the number of facilities with various research-related characteristics, including animal facilities, non-profits, and human subjects programs.

Exhibit 28. Characteristics of VA medical centers

<table>
<thead>
<tr>
<th>Number of VAMCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>With non-profit corporations</td>
</tr>
<tr>
<td>With human research programs</td>
</tr>
<tr>
<td>With animal facilities</td>
</tr>
</tbody>
</table>

Source: ORD.

Within VHA, the Office of Capital Asset Management & Support (OCAMS) provides policy, guidance, oversight, and budget management of the VA Major Construction, Minor Construction, and Non-Recurring Maintenance (NRM) programs, as well as leasing, space criteria, design, and planning. In order to be funded for improvements or new construction, projects to improve VA research facilities must be submitted and reviewed in competition with projects for clinical facilities as VA research does not have its own capital replacement plan. All renovations and construction projects are initiated at the facility, and submitted through the VISN to OCAMS at VA Central Office. In recent years, OCAMS staff has sought ORD input into funding decisions for minor construction and NRM projects, each of which can be submitted for a maximum of $9.9 million. Beginning in FY 2012, all VA construction and maintenance proposals are submitted to the Strategic Capital Investment Planning (SCIP) initiative. Through SCIP, board members and subject matter experts, look at major “gaps” in facilities to rank all projects. Funding level is then determined by senior leadership.59 In addition to minor construction and NRM projects, VA has recently awarded funding for several large-scale research facility projects,

59 Process description from key ORD informant, December 12, 2010
including research buildings at VA Puget Sound Health Care System in Seattle, WA, and VA Palo Alto Health Care System in California. These large scale projects are classified as Major Construction projects, which begin at $10 million and have no maximum cost limit.

**Condition of facilities**

In the interviews and in the survey, an opinion was frequently expressed that some VA facilities require renovation and that the poor state of the facilities was an impediment to the recruitment of researchers to VA. Many interviewees brought to our attention to the poor condition of research facilities. One informant mentioned that a Nobel laureate is working in deplorable conditions while teaching and mentoring other researchers. Interviewees believed that poor lab conditions hinder productivity and innovation, and may have a negative impact on recruitment.

Anecdotal information about the condition of facilities is supported by evidence. Exhibit 29A, for example, shows that of the 174 VA buildings assessed, 85 buildings (or 49%) were at least 50 years old. At the time of the study, ORD was in the process of completing a congressionally-mandated project to evaluate the physical infrastructure supporting the VA research program. The project assessing entailed conditions of research facilities at the 74 VA sites with VA research funding of at least $500,000. The architectural and engineering experts performed a technical assessment of biomedical laboratories, support space, and animal research facilities. An estimate of the cost to correct deficiencies at each site was prepared in accordance with industry standards; the estimate exceeded $774 million. The surveyors used a Facility Condition Index (FCI) to classify all buildings as being in good, fair, or poor condition. The industry-accepted parameters for facility conditions are as follows:

- Good condition = 0% – 5%
- Fair condition = 5% – 10%
- Poor condition = 10% and higher.

The vast majority of the buildings examined – 88% – were determined to be in poor condition and only seven buildings (4%) were found to be in good condition (Exhibit 29B). The FCI values for individual buildings were also averaged to generate campus-level FCIs. Using this calculation, none of the campuses were found to be in good condition.

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60 A Facility Condition Index (FCI) is an industry recognized and accepted means to quantify the condition of an asset, usually a building or facility with a number ranging from 0.00 to 1.00. The index is calculated by dividing the cost of deferred maintenance by the replacement value of the asset. In this case, the replacement value is determined to be the cost for building a new standalone facility of the same area with equivalent construction and systems (this is standard in the industry even for embedded partial facilities). Because the index is a fraction of 1.00, it is often expressed as a percentage, i.e.: 0.12 = 12%.
Exhibit 29. Condition of VA buildings

A. Distribution of buildings by the construction year

<table>
<thead>
<tr>
<th>Year Range</th>
<th>Number of Buildings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1897-1920</td>
<td>7</td>
</tr>
<tr>
<td>1921-1930</td>
<td>13</td>
</tr>
<tr>
<td>1931-1940</td>
<td>11</td>
</tr>
<tr>
<td>1941-1950</td>
<td>20</td>
</tr>
<tr>
<td>1951-1960</td>
<td>34</td>
</tr>
<tr>
<td>1961-1970</td>
<td>14</td>
</tr>
<tr>
<td>1971-1980</td>
<td>29</td>
</tr>
<tr>
<td>1981-1990</td>
<td>19</td>
</tr>
<tr>
<td>1991-2000</td>
<td>15</td>
</tr>
<tr>
<td>2001-2010</td>
<td>11</td>
</tr>
</tbody>
</table>

B. Distribution of buildings by the Facility Condition Index

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Buildings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good (0-5%)</td>
<td>7</td>
</tr>
<tr>
<td>Fair (6-10%)</td>
<td>12</td>
</tr>
<tr>
<td>Poor (&gt;10%)</td>
<td>153</td>
</tr>
<tr>
<td>ND</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: ORD.

ND=not determined.
N=173.

Access to facilities


HSPD-12 requires federal agencies to issue a "secure and reliable form of identification." The identification cards must be tamper and counterfeit resistant. The FIPS PIV standard requires issuance of specific identification cards which includes biometric data of the individual holding the identification card. Both of these standards apply to all federal research agencies, including VA.

To comply with these rules, VA must issue appropriate identification to students and interns who are interested in conducting research at VA. Regardless of their employment status or planned duties at VA, all personnel must undergo a background check and receive the appropriate training, including privacy and security awareness. We found no specific policies at VA related to facility access of interns and students. Medical students and residents who rotate through research labs as part of their medical training are handled by their local Graduate Medical Education office and university affiliates.

The delay associated with background checks affect all VA employees. However, it has particularly serious implications for the research program, which rotates medical students and interns on a frequent basis. Some of the ACOS interviewed stated that delays in obtaining background clearances prevent VA researchers from accepting interns or students to work on their research projects. Informants mentioned that it may take several months to clear a student who wants to volunteer for the summer, thus making the possibility of an internship unattainable. ACOS also pointed out that the unintended consequences of the human resources policies were lost recruitment opportunities, since interns and students who participated in research at VA are more likely to return for full-time employment.

We explored satisfaction with getting access to students and interns in the survey of researchers. We found that 58% of the respondents were not satisfied with the length of time required for students and interns to obtain access to research facilities (Exhibit 30).

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62 Key informant interview, #29, March 24, 2011.

63 Key informant interview, #43, April 22, 2011.
Exhibit 30. Satisfaction with access to facilities

Indicated your level of agreement with the following statement: “the length of time to obtain access to VA research facilities for students and interns is appropriate”

<table>
<thead>
<tr>
<th>Percent respondents</th>
<th>N=1,034</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>9</td>
</tr>
<tr>
<td>Satisfied/Strongly satisfied</td>
<td>16</td>
</tr>
<tr>
<td>Neutral</td>
<td>17</td>
</tr>
<tr>
<td>Unsatisfied/Strongly unsatisfied</td>
<td>58</td>
</tr>
</tbody>
</table>

Source: Abt Associates.
N=1,034.

While we did not explicitly asked about attainment of access for students and interns, we did examine in the survey the length of time it took to process a Without Compensation (WoC) appointment and to obtain access to VA facilities. For at least half of all respondents it took between one and six months to complete these processes (Exhibit 31). In some cases, it took seven months or longer. Note, however, that it is possible that VAMCs have established faster procedures for getting access for medical students and interns who work at local medical centers. These procedures have not been examined in the study.

Exhibit 31. Duration of time to obtain an appointment and access to facility

<table>
<thead>
<tr>
<th>WOC appointment</th>
<th>Access to facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 Month</td>
<td>11</td>
</tr>
<tr>
<td>1-3 Months</td>
<td>28</td>
</tr>
<tr>
<td>4-6 Months</td>
<td>45</td>
</tr>
<tr>
<td>7-9 Months</td>
<td>37</td>
</tr>
<tr>
<td>10-12 Months</td>
<td>14</td>
</tr>
<tr>
<td>&gt;12 Months</td>
<td>12</td>
</tr>
<tr>
<td>NA</td>
<td>38</td>
</tr>
</tbody>
</table>

Source: Abt Associates.
WoC=Without Compensation.
N=1,034.
How Moving Toward Community Based Outpatient Clinics Might Affect Research

As medical technology advances and pressures to rein in costs mount, an increasing portion of health care services is being delivered outside of traditional hospital setting in outpatient clinics. The creation of these super centers (known at VA as Community Based Outpatient Clinics, or CBOCs) and the inclusion of multiple services within them have provided VA with a unique opportunity to increase the availability of services to Veterans. Patient surveys indicate that Veterans are very satisfied with care they receive at CBOCs.64

While it is likely that outpatient clinics provide more efficient patient care, they may not be a suitable home for a research program. There are several reasons for this. First, services or procedures that require inpatient care might be unavailable in a CBOC, thereby reducing the scope of the research that could take place there. Second, the research support staff, such as biostatisticians, patient recruiters, and research administrators, may choose to remain at the traditional medical center, creating a barrier to conducting research in the super centers. Third, if a super center is geographically removed from medical centers, researchers working in such a facility may feel isolated from their colleagues at VA and from the vibrant academic community. As a result of some or all of these factors, outpatient facilities might be a less attractive setting for medical research adversely affecting recruitment and retention of talented physician-scientists to VA.

On the other hand, an outpatient health care center could also be an attractive setting for a researcher, if it offers multiple services for a variety of complex conditions and/or is located close to a large medical center. Furthermore, super centers could be less bureaucratic and more efficient in delivering care to Veterans and these efficiencies should be appealing to most physicians. Finally, super centers might help with recruitment of Veterans residing in geographical areas that are located far away from a VAMC.

Clearly, the CBOC model of care delivery has the potential to facilitate or to hinder research activities. In order to understand the possible consequences of moving patient care to outpatient clinics, we solicited the views of the research community on the super center model in key informant interviews and in the on-line survey.

We discussed the possible effects of super centers on the research programs with the Associate Chiefs of Staff (ACOS) at several medical centers. Of eleven respondents who expressed an opinion, nine appeared cautious about such move, one was positive about the idea, and one said that the consequences would be “disastrous” to his research program. This last individual told us that his research program was dependent on close relationships with academic affiliates and that a move to the super center could disrupt these crucial collaborative ties.

Respondents noted that administrative, oversight, and compliance challenges associated with conducting research at a CBOC might be insurmountable. For example, the main VAMC IRB would not automatically cover CBOCs, and thus CBOCs might have to arrange for their own IRB approvals. This respondent thought that CBOCs would be unwilling to take on this burden, especially if they operate under contract with VAMC and have negotiated their responsibilities.

On the positive side, one ACOS thought that super centers or CBOCs might increase accessibility to patient subjects because according to this respondent, Veterans expressed greater willingness to

64  https://www.hnfs.com/va/content/cboc/index.jsp.
participate in research if they could report to their local clinic. Respondents thought that for research projects that do not require laboratory equipment or research support – telemedicine was suggested as an example – the CBOC model could be viable, especially if the facility was not too far removed from the “mother-ship.” Finally, some ACOS said that they were already a super center and others told us that they have discussed the idea of collecting data at an outpatient clinic and were in principle interested in the concept.

To obtain more systematic data, we asked all researchers to indicate possible effects of super centers on the research enterprise. Depending on an option, between 25% and 30% of respondents reported having no opinion in the matter (data not shown). Of those who had an opinion, relationships with affiliates, and recruitment/retention of researchers to VA were seen as weak positives and access to patients and opportunity to start new research projects as strong positives (Exhibit 32). However, it was clear that the research community also had some reservations about the consequences of this move as respondents indicated a negative impact of super centers on access to data, equipment, students, and especially research support staff.

### Exhibit 32. Views on the consequences of moving towards a super center model

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Negative impact</th>
<th>No impact</th>
<th>Positive impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationships with affiliates</td>
<td>16</td>
<td>31</td>
<td>26</td>
</tr>
<tr>
<td>Access to data management systems</td>
<td>16</td>
<td>41</td>
<td>13</td>
</tr>
<tr>
<td>Access to research support staff</td>
<td>22</td>
<td>38</td>
<td>11</td>
</tr>
<tr>
<td>Access to students</td>
<td>17</td>
<td>37</td>
<td>14</td>
</tr>
<tr>
<td>Access to equipment</td>
<td>16</td>
<td>35</td>
<td>15</td>
</tr>
<tr>
<td>Access to patients</td>
<td>16</td>
<td>13</td>
<td>46</td>
</tr>
<tr>
<td>Retention of researchers at VA</td>
<td>16</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Recruitment of researchers to VA</td>
<td>16</td>
<td>29</td>
<td>26</td>
</tr>
<tr>
<td>Opportunity to initiate new research projects</td>
<td>15</td>
<td>13</td>
<td>46</td>
</tr>
</tbody>
</table>

Source: Abt Associates. Survey of VA researchers. Some negative/strong negative and some positive/strong positive percentages were combined into negative and positive, respectively. Individuals reporting no impact or selecting “no opinion” were included in the counts, but these data are not shown.

N=1,034.
Human Subjects Protection Program

Adequate protection of human subjects participating in research is instrumental to the development of diagnostic tools and therapeutic interventions. To protect human subjects and to promote ethical research, VA and 16 other federal departments and agencies adopted a set of regulations known as the Common Rule.65,66 The Common Rule established minimum standards for the ethical conduct of research, which must include an informed consent process, assessment of risks and benefits to the participants, and fair procedures for selecting study subjects. VA medical research that involves products regulated by the Food and Drug Administration (FDA) must also follow the FDA human subjects protections regulations.67 Institutional Review Boards (IRBs) are committees designated by each research organization to ensure human subjects research protocols adhere to the Common Rule and other applicable regulations via review, approval, and oversight.

One of the challenges faced by research organizations and IRBs is the consistent interpretation and application of the requirements specified in the human subjects regulations. For several reasons, this challenge is greater for VA. First, VA’s medical research program is based at more than 100 facilities across the country and includes thousands of research projects, which range from minimal risk to the human subjects (for example, analysis of hospital attendance data) to greater than minimal risk with no prospect of direct benefit to individual subjects (for example, clinical trials of new interventions). Second, VAMCs can use either their own IRBs or IRBs of affiliate universities, which increases the numbers of IRBs interpreting and applying the federal and VA-specific human research policies. Third, many VA research studies involve participants with mental illness or substance abuse problems, which might require “additional safeguards” to meet the regulatory requirements for vulnerable populations.68 Finally, the human subjects review process at VA is one of several steps that a research protocol must undergo as part of the R&D Committee review and approval process, creating potential coordination and timing challenges.

VA has had several widely publicized incidents and formal reviews that have been critical of its handling of human subject protections. In 1999, all human subjects research at the East Los Angeles VA Medical Center was suspended because of serious and long-standing patient safety problems.69 The following year GAO staff visited eight VA medical centers and found “various degrees of non-compliance with VA regulations and policies involving protections for human subjects.”70 The non-compliance involved the informed consent process and problems with the IRB review process, membership, and recordkeeping. However, GAO also acknowledged that significant corrective actions had been implemented at the three medical centers in response to prior regulatory sanctions. Another report released by GAO in 2003 found that the steps taken by VA to strengthen its human subject protections since the previous audit

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68 38 CFR 16.111(b).
were inadequate. Specifically, the report identified unclear training requirements, inadequate mechanisms to report adverse events, and insufficient resources allocated for human subjects protection activities.\(^{71}\) In 2008, the VA Office of the Inspector General reviewed informed consent procedures at 30 medical facilities and estimated that 31% of consent forms had some form of non-compliance.\(^{72}\)

Based on GAO reports and other sources, VA has taken many actions to improve compliance with human subjects regulations. In 2003, VHA was mandated via legislation to establish an Office of Research Oversight (ORO), which was tasked with monitoring responsible conduct of research, investigating alleged violations, and conducting prospective and for-cause reviews to ensure compliance with laws and regulations governing research.\(^{73}\) ORO is independent of the research program, reports directly to the Undersecretary, and is empowered to halt research projects due to violations. In 2000, VA signed a contract with the National Committee for Quality Assurance (NCQA) to begin accreditation of VA facilities. Between 2000 and December 2005, 72 VA facilities were accredited by NCQA. During this time, more VA facilities were accredited than all non-VA research programs throughout the world. In 2005, accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) became a requirement for all VA facilities. AAHRPP reviews include a self-evaluation and site visit that focuses on policies and procedures as well as quality assessment and improvement. By March 2011, virtually all VA facilities’ human research protection programs had been accredited by AAHRPP.\(^{74}\)

In addition, VA established the cross-ORD Program for Research Integrity Development & Education (PRIDE). This program provides all policy development, guidance, training, and education in human subjects protection across the agency. The educational component of PRIDE is the Center on Advice & Compliance Help (COACH).

Finally, to ensure the quality and efficiency of human research protections in VA multi-site studies, VA launched the VA Central IRB, which reviews all ORD-funded studies with more than one site engaged in research involving human subjects including the Cooperative Studies Program. The VA Central IRB is also currently piloting the review of one VA-NIH study, although VA has no capacity to expand beyond this one site at this time.

**Human subjects protection process at VA**

ORD requires that all individuals involved in human subjects research must complete two training courses, the Ethical Principles of Human Subjects Protection and Good Clinical Practice, every two years (until last year, the training was required annually). PRIDE is responsible for providing options to meet this training requirement, including on-line training developed with the Collaborative Institutional Training Initiative (CITI), or in-person training. Each VA facility director, in his/her role as Institutional Official of the local human research protection program, is responsible for ensuring that all personnel are up to date with the training requirements.


\(^{74}\) VA staff, personal communication.
Institutional Review Boards. All research involving human subjects conducted at VA (as well as all other research institutions) must be reviewed by an IRB prior to its initiation and it is the responsibility of the IRB to uphold the principles stated in the Belmont Report. According to VHA Handbook 1200.05, IRB has three authorities: to approve or disapprove a research protocol, to observe (or delegate to a third party to observe) the consent process and other aspects of research, and to suspend or terminate research which is not being conducted in accordance with IRB requirements or which has resulted in unexpected serious harm.

Regardless of its affiliation (e.g., VA facility or academic affiliate), the IRB must be composed of at least five voting members, diverse in racial and gender composition, and sufficiently qualified to be able to ascertain the acceptability of the proposed research protocol. It must include at least one voting member with scientific and one with non-scientific expertise and one voting member not affiliated with VA. The Handbook also instructs IRBs to make every effort to include a Veteran or Veteran representative. IRBs that regularly review research studies involving vulnerable populations are to consider including individuals who have knowledge and experience working with these populations.

The IRB reviews the research protocol and associated documents, such as recruitment materials, informed consent forms, and data collection instruments. To qualify for approval, the research must satisfy all of the following criteria from 38CFR16.111 and the 1200.05 Handbook:

- The risks to subjects are minimized and are reasonable relative to anticipated benefits
- Selection of subjects is equitable
- Informed consent procedures are appropriate
- Provisions to ensure safety, confidentiality, and privacy of the subjects are adequate
- Information security policies are implemented and monitored
- Additional safeguards are in place for vulnerable populations
- Procedures to manage, reduce, or eliminate conflicts of interest are in place
- Investigator has the appropriate qualifications
- Protocol, informed consent, and the HIPAA authorization are consistent.

Use of informed consent with vulnerable populations. According to federal regulations, individuals who are mentally disabled or have impaired decision-making capacity are defined as a vulnerable population. These study populations are considered vulnerable to coercion. VA periodically assesses the types of conditions that would classify the person they affect as vulnerable. For instance, a recent study of Veterans with PTSD concluded that they did not need to be deemed categorically vulnerable and that existing protections were sufficient. Currently, the following categories are considered at VA

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78 Should Veterans with a Diagnosis of Post-Traumatic Stress Disorder Be Considered a Vulnerable Population for the Purpose of Applying Guidelines for the Protection of Human Subjects in Research? Report of a Work Group
as potentially vulnerable: fetuses, neonates, pregnant women, prisoners, children, and subjects lacking decision-making capacity. 79 We did not find any special provisions in VA policy for persons with mental illness and/or substance abuse due to the fact that not all individuals with mental illness and/or substance abuse have impaired decision-making abilities.

The Common Rule and VA policy include several provisions regarding protection of vulnerable populations:

- IRBs must consider the following criteria for approval of research: “When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects” (38 CFR 16.111b).
- IRBs must review any additional safeguards to protect these vulnerable subjects, such as use of surrogate consent (Office of Research Oversight Human Research Protection Program (HRPP) Checklist, February 2011).
- For IRBs that regularly review research involving mentally disabled persons, IRB membership should include individuals with relevant expertise “who are knowledgeable about and are experienced in working with these subjects” (38 CFR 16.107a).
- IRBs must ensure the study includes appropriate procedures for respecting dissent, and consider whether or not the study needs to include procedures for obtaining assent (1200.05).
- Investigators are responsible for identifying vulnerable populations susceptible to coercion or undue influence and any additional safeguards to protect these populations (1200.05).

Handbook 1200.05 also may require an increased frequency and/or focus of audits by the Research Compliance Officer for studies involving vulnerable populations.

Guidelines for termination of studies due to adverse events. An Adverse Event (AE) is “any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article.” 80 VHA Handbook 1058.01 provides further clarification of which types of Adverse Events or Problems are considered serious, as follows:

- A Serious Adverse Event (SAE) results in “death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect.”
- A Serious Problem (SP) results in “harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of research subjects, research staff, or others.”
- “An AE or problem ... is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent” SAE or SP.
According to VHA Handbook 1200.05, a termination of IRB approval is “a determination by the convened IRB to permanently halt some or all previously approved research activities including, but not limited to, enrollment of new subjects in research.” As noted above, IRBs have the authority to “suspend or terminate approval of research that is not being conducted in accordance with IRB’s requirements, or that has been associated with unexpected serious harm to subjects” (see 38 CFR 16.113, VHA Handbook 1058.01). The terms “unexpected” or “unanticipated” are defined as “an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.”

This handbook further defines procedures for reporting these types of incidents to the IRB, VA facility director and ORO (Exhibit 33).

After receiving reports, the IRB reviews the events and can decide to temporarily suspend or terminate the research (we could not find any concrete guidance on how this decision is to be made). Other possible determinations include requiring modifications to the study protocol, providing additional information to subjects, and requiring additional monitoring.

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81 VHA Handbook 1058.01.
Exhibit 33. Procedures for reporting adverse events

Use of internal versus affiliate IRBs by VA medical centers. VA requires that each medical center establishes its own IRB or secure the services of another IRB, at an academic affiliate or another VAMC. Facilities using affiliate IRBs must put in place a Memorandum of Understanding (MOU) specifying how the facility and the affiliate will collaborate on supporting the IRB and on the protection of human subjects.82

According to the data for FY2010 provided by ORD, roughly half of VAMCs use their own IRB (51 of 104 or 49%, Exhibit 34). We examined the relationship between the use of an IRB and the size of the research program based on FY2010 VERA allocations. We found that 40% of VAMCs with small research programs (total VERA allocation of less than $5 million) use their own IRBs, compared to 62% of VAMCs with medium research programs (total VERA of $5–30 million), and 46% of VAMCs with large research programs (total VERA of more than $30 million). Facilities with medium and large research programs rely exclusively on their own or on an affiliate IRB. Based on the interviews, collaborative projects between affiliates and VA are often (although not always) reviewed by two IRBs, as neither universities nor VA generally accept the other’s determination.

Exhibit 34. Use of IRBs by the size of the research program

Source: Office of Research and Development.
The size of the research program was based on the total VERA dollars for FY2010. Dollar ranges for small, medium, and large facilities were suggested by ORD.

N=104.

VA Central IRB. The VA Central IRB was established in 2008 to review ORD-funded multi-site research projects involving human subjects. VA literature suggests that VA Central IRB has several advantages over local IRBs, such as centralized investigator accountability, earlier identification of adverse events, decreased likelihood of conflicts of interest, and more efficient IRB review. VA Central IRB meets monthly in Washington, DC and/or via video- or teleconferencing. It is composed of 17 voting members and 5 non-voting members and includes expertise in science, medicine, law, ethics, information security, regulatory affairs, and other subjects. Ad hoc advisors are recruited when needed. VA Central IRB has been accredited by AAHRPP.

All ORD-funded studies with more than one site engaged in human research are reviewed by the VA Central IRB. When the application is approved (or is subject to approval pending minor changes), VA

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Central IRB sends the determination letter to the PI and a copy of the application package to all the sites participating in the study. The sites are allowed 30 days to provide comments to VA Central IRB. Final approved package is sent to all sites, and is reviewed by the local R&D Committee along with other materials.

**Process for the approval of research.** PIs and other investigators must have completed all educational requirements for the protection of human subjects prior to merit review. IRB reviewers are instructed to consider whether “the study places human subjects at risk of physical or psychological harm, and the adequacy of provisions to minimize risk, protect participants’ privacy and the confidentiality of their records or responses, ensure informed consent, and minimize respondent burden.” In addition, the reviewers are responsible for considering whether women and minorities are adequately represented as study subjects.

In addition to federal regulations, VA researchers must comply with VA policies and procedures governing research with humans. VA policy stipulates that a research project cannot be initiated until it is approved by the VA R&D Committee, which reviews and evaluates the decisions of all applicable subcommittees, including IRB, Institutional Animal Care and Use, or Safety. Exhibit 35 illustrates the steps required to obtain permission to conduct research involving human subjects.

**Exhibit 35. Process to obtain approval to begin research and of post-initiation oversight**

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**Source:** H. H. Birdsall and R. D. Rossen. Research Handbook: Information needed to successfully submit proposals to the Institutional Review Board, Research and Development Committee and funding agencies. 2010 and key informant interviews.

Note: Approval for submission (far left) only required for VA-funded research.

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86 For example, Pilot Reviewers. Tips for Preparing. March 2011.
Oversight of human subject protection process

As mentioned earlier in this chapter, the creation of ORO was mandated by Public Law 108-170 to “monitor, review, and investigate matters of medical research compliance ... and the protection of human subjects and Department employees participating in research.” ORO engages in three types of activities:

- On-site reviews and inspections
- Remote compliance reviews
- Education and training assistance.

ORO includes 23 staff members in its Central Office and 30 staff members in its five regional offices. Each regional office oversees 20–30 research facilities. ORO staff has grown from 28 FTEs in 2003 to 53 in 2010 and its budget from $4.8 million to $11.6 million over the same time period (data not shown). As of 2009, each research facility is required to support at least one Research Compliance Officer, whose primary function is to conduct mandatory informed consent audits (annually) and regulatory audits (every three years).

ORO conducts both announced and unannounced visits each year (most are announced). Of these, 10–15% are conducted “for cause,” to investigate allegations or potential cases of serious non-compliance. The remaining 85–90% are routine, proactive inspections to ensure organizational compliance with VA and federal human subjects regulations. As depicted in Exhibit 36, the number of on-site audits per year has increased from 19 in 2003 to over 100 in 2010, of which 13 were for cause. The goal of ORO is to maintain the number of visits at 90–100 per calendar year. ORO requires that facilities develop “remedial action plans” to resolve any non-compliance issues identified during on-site visits. These plans are monitored by ORO until all remedial actions are implemented. The number of remedial action plans monitored by ORO has grown from 29 in 2003 to 218 in 2010 (data not shown).

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90 Ibid.

91 Ibid.

92 Ibid.
In addition to facility visits, ORO conducts remote reviews of human subjects protections processes. These include the assessment of:

- Non-serious or continuing deficiencies
- Certifications of research oversight based on facility self-assessment
- Non-compliance events identified by the facility or by the local Research Compliance Officer
- Adverse Events and problems in research.

In 2010, ORO reviewed 335 cases of non-compliance identified by facilities and 356 by Research Compliance Officers and 18 Adverse Events/problems (data not shown). The same year, ORO introduced a series of indicators to measure the outcomes of VA human subject protection activities in 16 areas. These indicators were conceived of as a potential tool for more quantitative assessment of human research protection programs, which would facilitate comparisons between facilities and guide improvement decisions. The development of indicators followed an extensive consultation and deliberation process involving experts in human subject protection within and outside of VA. Example indicators include accreditation status, number of protocols initiated without IRB and/or R&D Committee approvals, number of for-cause suspensions and serious adverse events, number of educational activities related to research with human subjects, and many others.

Finally, in addition to compliance monitoring, ORO carries out educational and technical assistance activities. These include developing and distributing guidance documents, attending network meetings, and conducting regular nationwide compliance telephone conferences.

**Research community views**

To collect data for this Research Issue, we interviewed a diverse group of VA researchers and administrators involved in the protection of human subjects at the national and local levels. Through

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these interviews we examined perspectives on the coordination of the human subjects review process, coordination of the accreditation process, the use of informed consent with vulnerable patient populations (including substance abusers and the mentally ill), compliance oversight, and guidelines for termination of studies due to adverse events.

The VA research program is a vast network of diverse facilities, each with unique needs. As a result, VA has instituted national policies that all facilities must follow while also allowing the facilities to tailor their individual policies and regulations to the unique needs of their research communities, study populations, and relationships with affiliates. In general, researchers and IRB experts interviewed appreciated the facility-level flexibility allowed by the policies. However, the prevailing view from these groups was that they are completely overburdened by compliance policies and regulatory loads related to ORO and accreditation by AAHRPP as well as ensuring consistency between local facility and national VA policies. Many viewed these burdensome requirements as detracting from efforts that more directly result in protection of human subjects.

Significant regulatory burden is not unique to VA. According to the interviewees, policies related to the protection of human subjects and to data security have become much more stringent for all research institutions. However, some interviewees viewed the burden of VA policies as excessive even in today’s increasingly regulated environment. For example, we had many discussions about the revised VHA Handbook 1200.05. Although the purpose of the revisions was to clarify and exemplify many human subject regulations, some researchers and administrator believed that it had the opposite effect. A view was expressed that the document is now 100 pages long and is burdensome to read. Respondents also noted that many of the new guidelines were either unclear or contradicted old regulations without adequate explanation, thus increasing potential for non-compliance and lessening human subjects protections. As one ACOS stated, “the more you change things the more the investigator becomes confused and accidentally does the wrong thing.”

Insufficient communication was mentioned in many interviews. For example, we heard that a unified message from ORO and ORD about the need for various requirements would help improve morale and the implementation of these requirements in the field. IRB administrators said that they would appreciate the opportunity to meet with colleagues from other facilities in order to share experiences and identify best practices.

94 Interview #12. February 2, 2011.
95 Ibid.
96 Interview #25. May 2, 2011.
97 Interview #52. May 25, 2011.
98 Interview #12. February 2, 2011.
100 Interview #35. April 18, 2011.
102 Interview #53. June 2, 2011.
103 Interview #36. April 13, 2011.
Respondents were also in agreement that ORO and ORD policies are burdensome. Researchers, ACOS, and IRB administrators alike expressed the view that policies related to human subjects research are designed to protect VA the institution rather than VA human subjects. Respondents believed that a thoughtful re-evaluation of policies and compliance activities is necessary in order to improve human subjects protections. All advocated eliminating redundant policies and enforcing only those policies that actually protect human subjects.104

Respondents had mixed opinions about the coordination of ORO and the VA’s accreditation organization, AAHRPP. A handful of respondents saw value in the AAHRPP accreditation process. For example, one national-level official viewed the AAHRPP accreditation as beneficial, because it forces each VA facility to conduct a self-assessment of every policy and procedure,105 while another thought it was a great standardization effort across diverse facilities.106 An ACOS stated that AAHRPP provides clear guidance and works closely with local facilities to identify and fix compliance violations that arise during inspections.107 Another ACOS mentioned that AAHRPP has become an important source of education for compliance with human subjects regulations and consultative guidance for his facility.108

However, the majority of those we spoke with expressed the view that AAHRPP accreditation was an arduous and contentious process that is most likely not improving the protection of human subjects in VA research. Many IRB administrators and ACOS expressed frustration over the extraordinary amount of time and resources it takes to prepare for and host a visit by AAHRPP.109,110,111 Others felt that due to the qualitative nature of the AAHRPP review, the findings were subjective and therefore less likely to add to human subject protections, especially in contrast to the more quantitative accreditation process under the National Committee for Quality Assurance (the organization that preceded AAHRPP).112

Similarly, a spectrum of opinions was expressed regarding ORO compliance reviews. Some respondents at the national level stated strong support for and confidence in the ORO compliance reviews.113 However, many researchers and IRB administrators had a much more contentious view of this process. A number of researchers expressed a view that ORO has become excessively focused on policing and much less on education and assistance, a view that ORO staff contested.114 ACOS told us that they feel constantly threatened with shutdowns of their research programs because of the slightest misstep.

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104 Interview #53. June 2, 2011.
105 Interview #35. April, 18, 2011.
106 Interview #17. March 2, 2011.
107 Interview #29. April 24, 2011
108 Interview #33. April 19, 2011.
110 Interview #52. May 25, 2011.
111 Interview #31. March 30, 2011.
112 Ibid.
113 Interview #31. March 30, 2011.
114 Interview #33. April 19, 2011.
Respondents repeatedly use the expression “climate of fear” to describe VA. Some ACOS expressed dismay that they and their research communities cannot be entrusted with protecting the Veterans.

Regardless of individual opinions on AAHRPP and ORO compliance reviews, researchers and IRB administrators almost universally expressed frustration over the burden of compliance reviews and audits from both AAHRPP and ORO. Respondents felt that there was a tremendous amount of overlap between the two reviews and very little explanation why dual reviews were needed. Furthermore, researchers told us that in some cases overall findings from AAHRPP and ORO were in conflict, causing confusion. These discrepancies have made many researchers question the validity and overall benefit of the AAHRPP and ORO reviews. Many expressed an urgent need for a clear, non-duplicative, more relevant, and less labor-intensive compliance review process.

Overwhelmingly, respondents expressed a view that VA’s research program does an exceptional job protecting vulnerable populations, particularly those with mental illness and substance abuse problems. In fact, some felt that VA provides superior protection to these populations compared with academic research programs. VA researchers and IRBs view themselves as advocates for Veterans and are very protective of them. As one IRB administrator stated, all Veterans were vulnerable because of what they had been through and thus required special protections.

We also heard universal praise for informed consent processes for Veterans suffering from mental illness or substance abuse, even though VA does not offer any specific guidance or regulation in this area. The researchers and local IRB administrators said that they simply follow the Common Rule and general VA policies regarding additional safeguards for vulnerable populations; specific requirements related to informed consent are set forth by local IRBs.

Despite the individualized nature of informed consent processes at VAMCs, interviewees mentioned two common strategies that were often used by IRBs to provide extra protections to vulnerable populations. The first strategy was the use of certificates of confidentiality for research projects that collect information on illegal drug use. These certificates protect VA researchers against court orders or subpoenas that would compel them to disclose damaging information about the Veterans.

The second strategy was the use of mental health experts on IRB panels. A number of IRB administrators and researchers that we spoke with stated that the local policy at their facility was that any VA study protocol that includes participants with mental illness or substance abuse problems must be reviewed by a psychiatrist or other mental health professional. This expert review is designed to provide an extra protection for vulnerable populations. The prevailing view, expressed by VA

115 Interview #35. April, 18, 2011.
116 Ibid.
117 Interview #31. March 30, 2011.
118 Interview #36. April 13, 2011.
120 Interview #31. March 30, 2011.
121 Interview #33. April 19, 2011.
122 Interview #52. May 25, 2011.
administrators and researchers, was that these additional protections, which are implemented at the discretion of the local IRBs, were successful in protecting subjects with mental illness and substance abuse problems in VA research.

Termination of studies due to adverse events in VA research is rare. As a result, the majority of the VA researchers and administrators that we interviewed had limited experience with this process. However, the prevailing view expressed by researchers and VA staff was that the local IRBs are effective in reporting adverse events to ORO when they occur and following the guidelines for termination of studies. One administrator within ORO stated that although the termination of studies is determined by the local IRBs, any variability that is seen in decision-making is due to local IRBs being too conservative in their rulings and shutting down studies prematurely, rather than being too lax and allowing potentially dangerous studies to continue.

Although we heard praise for local IRBs once an adverse event was reported, a number of researchers and officials also felt that there was a great deal of confusion in the research community about this process. As one official stated, “it’s impossible to figure out what to report, so the researchers basically report everything and hope for the best.” The newest VA handbook (1200.05) was praised for providing more guidance to researchers on what types of events to report; however, we heard a universal call for continuing education in this area. In particular, multiple respondents recommended establishing an “adverse events log,” which would provide PIs with common examples of adverse events that have to be reported.

The results from the investigator survey were similar to the feedback we received from the interviews. Investigators were satisfied with human subjects protection training at VA: 70% of survey respondents agreed or strongly agreed that the quality of the training was high, while less than 7% disagreed or strongly disagreed with that statement (Exhibit 37). Similarly, nearly 80% of investigators believed that VA was very successful in protecting vulnerable human subjects, such as the mentally ill, and less than 2% of investigators disagreed or strongly disagreed with that statement (data not shown).

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123 Interview #44. April 29, 2011.
124 Interview #35. April, 18, 2011.
125 Ibid.
126 Interview #53. June 2, 2011.
127 Interview #45. May 13, 2011.
Exhibit 37. Quality of training programs for human subjects protection

*Indicate your level of agreement with the following statement: “The quality of training is high”*

<table>
<thead>
<tr>
<th></th>
<th>Percent respondents</th>
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<tr>
<td>Strongly Disagree</td>
<td>1</td>
</tr>
<tr>
<td>Disagree</td>
<td>5</td>
</tr>
<tr>
<td>Neutral</td>
<td>13</td>
</tr>
<tr>
<td>Agree</td>
<td>45</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>25</td>
</tr>
<tr>
<td>NA</td>
<td>10</td>
</tr>
</tbody>
</table>


However, views of the research community diverged when it came to the coordination of human subjects protection process. Forty percent of respondents either agreed or strongly agreed that the human subjects review process was well coordinated, 19% were neutral, and 30% either disagreed or strongly disagreed with the statement (Exhibit 38).

Exhibit 38. Coordination of human subjects review process

*Indicate your level of agreement with the following statement: “the human subjects review process is well coordinated”*

<table>
<thead>
<tr>
<th></th>
<th>Percent respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly Disagree</td>
<td>9</td>
</tr>
<tr>
<td>Disagree</td>
<td>21</td>
</tr>
<tr>
<td>Neutral</td>
<td>19</td>
</tr>
<tr>
<td>Agree</td>
<td>32</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>8</td>
</tr>
<tr>
<td>NA</td>
<td>11</td>
</tr>
</tbody>
</table>

VA investigators expressed substantial discontent with the amount of time it takes to complete the human subjects review process. Only 29% of respondents agreed or strongly agreed that the time required for the human subjects review process was appropriate, compared to 46% who disagreed or strongly disagreed with this statement (Exhibit 39).

**Exhibit 39. Duration of the human subjects review process**

*Indicate your level of agreement with the following statement: “the length of time required for the human subjects review process is appropriate”*

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>29</td>
<td>14</td>
<td>25</td>
<td>4</td>
<td>11</td>
</tr>
</tbody>
</table>

N=1,034.*

To get an estimate of compliance burden on the facilities, we asked ACOS to estimate the number of hours needed to prepare for compliance-related visits and to host the visits. Respondents reported spending hundreds of hours on these visits (Exhibit 40). For example, an average number of hours to prepare and host AAHRPP (human subjects accreditation) was 585 (data not shown). According to the data, 84 ACOS and their support staff spent a total of 92,597 hours to prepare and host all compliance-related visits (data not shown). As there are 109 VAMCs with research programs, we estimate the total compliance burden at over 120,000 hours or 58 FTEs (at 2,080 hours per FTE).
Exhibit 40. Number of hours spent in 2010 by ACOS on compliance-related inspections


N=86.

AAHRPP: Association for the Accreditation of Human Research Protection Programs
AAALAC: Accreditation of Laboratory Animal Care
USDA: US Department of Agriculture
OSHA: Occupational Safety and Health Administration
SOARS: Systematic Ongoing Assessment and Review Strategy
ITOC: Information Technology Oversight and Compliance
ORO: Office of Research Oversight – Research & Development
AWE: VISN Annual Workplace Evaluation
EOC: Environment of Care
IACUC: Institutional Animal Care and Use Committee
OIG: Office of Inspector General

Biosafety and Biosecurity Program

At VA, policies regulating environmental issues related to the use of toxic agents fall into two main categories: 1) ensuring VA personnel safety from toxic agents that are used in VA research laboratories\(^\text{128}\) (referred to from this point forward as biosafety) and 2) preventing and/or detecting terrorist events occurring in or originating from select agents and toxins used in VA research laboratories\(^\text{129}\) (referred to from this point forward as biosecurity). The use of toxic agents in research can be a dangerous endeavor, for personal safety as well as national security reasons. As a result, the VHA R&D program operates its laboratories in compliance with policies, statues, and regulations of

\(^{128}\) VHA Handbook 1200.08.

\(^{129}\) VHA Handbook 1200.06
appropriate federal agencies including VA, the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), the Department of Health and Human Services (HHS), the United States Department of Agriculture (USDA), and any applicable state or local regulations. In addition, all applicable guidelines issued by HHS, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), USDA, the United States Postal Service (USPS), and the Animal and Plant Health Inspection Service (APHIS) must be followed. In order to comply with these many federal agency regulations, as well as additional VA-specific policies, an extensive set of policies and procedures has been put in place to regulate the use of toxic agents in VA research.

**Biosafety**

Handbook 1200.08 describes VA policies and procedures related to the safety of personnel engaged in research. This handbook was designed to keep the VA research program in compliance with the many federal regulations related to toxic agents and other potentially hazardous materials. Specifically, this handbook explains the procedures that are to be followed when using potential hazards encountered in VA research settings. These potential hazards include but are not limited to:

- **Biohazards** such as: 1) pathogens and etiologic agents, human and non-human primate tissues including blood and body secretions, and human cells; 2) toxins produced by microbial organisms; 3) poisonous, toxic, parasitic, and venomous animals or plants; 4) recombinant DNA molecules; 5) select agents (agents such as viruses, bacteria, rickettsiae, fungi, toxins, and recombinant DNA that have been designated by CDC as requiring registration with the CDC Laboratory Registration Program); and 6) animals experimentally or naturally exposed to any of the preceding.

- **Chemical hazards** which include any substance or mixture of substances with properties producing adverse effects on the health and safety of humans including 1) corrosives; 2) toxic substances; 3) sensitizers; 4) carcinogens, mutagens, and teratogens; 5) flammables; and 6) explosives.

- **Physical hazards** such as: 1) ionizing and non-ionizing radiation; 2) noise; 3) vibration; 4) extremes of temperature and pressure; 5) explosive hazards; 7) mechanical hazards.

In addition to detailing the hazards subject to oversight, the 1200.08 handbook also describes the regulatory committees that must be in place to regulate the use of these hazards as well as the process VA researchers must follow before including any of these materials in their research studies. These procedures are described in greater detail below.

In order to stay in compliance with VA policies and federal statutes governing the use of toxic agents, all VA research programs must develop and maintain a comprehensive Research Safety Program. One

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130 Ibid.
131 Ibid.
132 VHA Handbook 1200.08.
key component of a comprehensive program is the Safety (biosafety) Plan. The Safety Plan must cover all VA research laboratories and meet the following requirements:133

- Meet the biosafety standards and requirements for BSL-2, BSL-3, and BLS-4 operations as they pertain to the respective select agents and toxins that are contained in the most recent edition of the CDC-NIH Publication, “Biosafety in Microbiological and Biomedical Laboratories”

- Follow all applicable OSHA guidelines

- Be commensurate with the risk of the agents in use, and there must be sufficient information available to describe the biosafety and containment procedures

- Incorporate the NIH “Guidelines for Research Involving Recombinant DNA Molecules” requirements for portions of the safety plan related to genetic elements, recombinant nucleic acids, and recombinant organisms

- Include applicable sections of the “NIH Guidelines for Research Involving Recombinant DNA Molecules”

- Specifically state that certain experiments (experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire that trait naturally or experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates) may not be conducted unless approved by the HHS Secretary after consultation with experts

- Include the emergency response program, in accordance with 29 CFR 1910.38 and its requirement for drills to test implementation of the plan

- Be reviewed at least annually and revised as necessary

- Include as mandatory regular (at least annual) safety inspections and drills or exercises conducted to test and evaluate the effectiveness of the plan

- Identify, record, and correct any deficiencies identified as a result of the inspections.

In addition, laboratories that work at BSL 3 containment must maintain a separate, written, regularly updated laboratory manual that includes standard operative procedures and emergency procedures in a variety of situations such as spills, power outages, and breaches of security.

**Biosecurity**

For many years, biosafety was the primary focus of VA policies and procedures on the use of toxic agents and other hazards in VA research settings. However, in the wake of the September 11th attacks and the anthrax scare of 2001, VA was compelled to establish procedures related to select agents and toxins used in research in order to prevent and/or detect terrorist events occurring in or originating from VA research laboratories.134 As President Obama stated in Executive order 13546,135 a robust and

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133 VHA Handbook 1200.06
134 Interview #49. May 6, 2011.
productive scientific enterprise that utilizes biological select agents and toxins is essential to national security. However, select agents and toxins must be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release. Moreover, biosecurity measures must be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of these hazardous materials. As a result, Handbook 1200.06 was created. The purpose of this document was to provide physical and organizational controls for the storage and use of select agents, toxins and other highly dangerous hazardous agents. The handbook addresses biosecurity policies that are distinct from those relating to biosafety, although the requirements for biosecurity and biosafety overlap.\(^{136}\)

According to the Handbook, each VA facility housing research laboratories is required to develop and maintain a comprehensive Security Plan, which provides protections commensurate with the risk.\(^{137}\) The Security Plan must include the description of the threats and security controls as well as policies and procedures for acquiring, using, maintaining, and disposing of biohazards.

Finally, each VA facility with research laboratories must also develop and implement an Emergency Preparedness and Response Plan. This plan must be updated annually and must address research laboratories at approved off-site locations.\(^{138}\) VA facilities are cited as out of compliance if they do not have a safety plan, security plan and emergency preparedness and response plan.

**Coordination of biosafety and biosecurity**

In order to ensure that the biosafety and biosecurity plans are properly implemented, VA has also established a number of committees and positions to oversee the regulation of toxic agents as part of Research Safety Programs. However, given the great diversity in use and types of toxic agents and hazardous materials utilized across VA research studies, individual facility sites have been able to develop unique Research Safety Programs that are most relevant to their needs and hazards found on site.\(^{139}\) Every VA facility conducting research with potential safety hazards must establish either a Subcommittee on Research Safety (SRS) or an Institutional Biosafety Committee (IBC), or secure the services of an analogous committee at another VA or university affiliate.\(^{140}\) The SRS (or analogous committee) is the primary committee that reviews and approves VA research projects for biosafety and biosecurity. Facilities that conduct research which has been judged to have no safety issues or hazards are exempt from establishing an SRS committee; however, this is rare in VA research.\(^{141}\)

According to VHA Handbook 1200.08, the SRS was established by R&D and is responsible for reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines. Approval must be obtained prior to submission for

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\(^{136}\) Ibid.

\(^{137}\) Ibid.

\(^{138}\) VHA Handbook 1200.06.

\(^{139}\) Interview #49. May 6, 2011.

\(^{140}\) VHA Handbook 1200.08.

\(^{141}\) Interview #44. April 29, 2011.
funding to ORD and prior to onset of any research project, regardless of funding.142 Researchers must first submit VA Form 10-0398 to the SRS, which details all safety issues related to the proposed research protocol and helps Principal Investigators self-identify potential hazards in the research they are proposing.143 Once a study protocol is reviewed and approved by the SRS, the protocol is passed along to R&D for final approval. All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the R&D Committee prior to commencement.144

Additional responsibilities of the SRS include reviewing annually all active research protocols involving biological, chemical, physical and radiation hazards, regardless of funding source and coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees.145 The requirement to have a committee such as the SRS review and approve all study protocols before initiation is unique to VA. While other research organizations typically require an Institutional Review Board to protect human subjects and an animal safety committee to protect animal subjects, most do not require an additional safety committee to review research protocols.146

It is recommended that the SRS include members from the facility safety committee, the Institutional Animal Care and Use committee (IACUC), the Radiological Safety Officer, and a liaison from an affiliated university Institutional Biosafety Committee.147 It is also recommended that at least one SRS member possesses specific occupational safety and health, environmental, and Department of Transportation expertise to ensure that all pertinent hazards in protocols are identified.148 The 1200.08 handbook also requires that each SRS must have at least five members when the research review involves recombinant DNA not exempt from the current NIH Guidelines for Research Involving DNA Molecules.149 In addition, it is usually necessary for the SRS membership to possess expertise in 1) etiologic agents, including bloodborne and airborne pathogens; 2) chemical carcinogens and other chemical hazards; 3) and physical and radiation hazards. The facility director appoints the SRS chairperson for a term of 1 year and this chairperson can be reappointed.150 All agendas and minutes of the SRS must be prepared according to the format specified in the VHA Handbook 1200.08. For each new project, the committee can vote that a research protocol is approved, approved pending clarification, deferred, or disapproved.151

142 VHA Handbook 1200.08.
143 Interview #49. May 6, 2011.
144 VHA Handbook 1200.08.
145 VHA Handbook 1200.08.
146 Interview #49. May 6, 2011.
147 VHA Handbook 1200.08.
148 Ibid.
149 Ibid.
150 Ibid.
151 Ibid.
Training requirements

Given the wide array of chemicals, toxic agents, and other hazardous materials used in VHA research, as well as the many training requirements of government agencies such as OSHA and CDC, VHA biosafety and biosecurity training programs are individualized to the specific needs of the VA facility and researcher. Prior to beginning of their duties, all VHA laboratory staff members are required to view the Biosecurity Training Presentation and training on the Laboratory’s Emergency Preparedness and Response Plan. As it is specified in VHA Handbook 1200.06, training requirements must also include:

- General information on safety and security within VA research laboratories as well as safety, security, containment, and transferring of hazardous agents including select agents or toxins
- Specific information related to the laboratory in which they will work and to the agents with which they will work
- Training requirements set forth by OSHA, CDC, other applicable federal agencies, and other VA policies.

Research community view

To gain a better understanding of environmental issues related to the use of toxic agents in VA research, we spoke with several knowledgeable individuals at VA and included several questions on the subject in the investigator survey. In the interviews, we learned that VA has a strong and effective program in biosafety and biosecurity. One area of strength that was cited by a few of the individuals was the SRS committee, which operates similarly to IRBs. Unlike most other research institutions, VA requires this extra level of review before any research involving biological, chemical, or physical agents or radiation can be initiated. Although the respondents we interviewed acknowledged that requiring all research protocols to pass through an extra layer of review posed a large administrative burden, they felt that the benefits of this process outweighed the negatives aspects. In particular, they indicated that the SRS provides a formal and standardized mechanism for evaluating the safety of research and offers a reporting mechanism if a problem with biosecurity and biosafety occurs. As a result, our respondents believed this process makes researchers and their subjects at VA safer than at other research institutions.

While there was a lot of discontent among the interviewees about the processes of IT security, HR, and contracting, we heard very few problems regarding the biosafety and biosecurity program. When asked

152 Interview #49. May 6, 2011.
154 VHA Handbook 1200.06.
155 Ibid.
156 Interview #49. May 6, 2011.
157 Interview #25. May 2, 2011.
158 Ibid.
159 Interview #49. May 6, 2011.
what might set this program apart from other regulatory processes, one official thought that regulating toxic agents is easier because people more readily understand the inherent dangers in using hazardous materials and are, therefore, more willing to accept administrative burdens.\footnote{Interview #25. May 2, 2011.} Another individual suggested that while the safety inspection teams are focused on compliance, when they find problems, they also do their best to explain why a site was not in compliance and often provide guidance on how to fix the problem before leaving.\footnote{Interview #49. May 6, 2011.} It was suggested that this focus on education and problem solving assistance is lacking from some of the other regulatory processes and as a result triggers more opposition from investigators and administrators.

A few concerns about the biosecurity and biosafety programs were brought to our attention in the interviews. Respondents pointed out that having two Handbooks, 1200.08 and 1200.06, addressing the same issues of environmental protection was confusing and caused problems in the field.\footnote{Ibid.} Specifically, we heard that there were some conflicting policies and procedures between the two handbooks, such as the regulations related to non-affiliated members of safety committees, age minimums, and alternatives to onerous requirements.\footnote{Interview #49. May 6, 2011.} Our respondents recommended that the two handbooks be combined into one comprehensive document that incorporates the current regulations, clarifies conflicting statements, and complies with the standards from federal agencies such as OSHA and the CDC.\footnote{Interview #25. May 2, 2011.}

Another concern raised by those we interviewed focused on training programs. We heard that due to the very specific requirements that exist for individual toxins and hazardous materials, various training programs have been created that educate the research community about specific narrow topics, which can add to regulatory burden and confusion.\footnote{Interview #49. April 28, 2011.} On the other hand, a single training program that covers all components of biosecurity and biosafety might be overwhelming and an unproductive use of time for most VHA researchers and staff. Improving communications and providing opportunities for collaboration and joint problem solving was offered as a possible alternative. One individual suggested that conducting monthly webinars or conference calls as well as releasing bulletins on hot topics related to recent policy changes would provide opportunities for collaboration and problem solving that do not normally occur in the current system.\footnote{Ibid.}

Finally, we also heard that although there are extensive training requirements for investigators and staff working directly in VA laboratories, VA research leadership often is not properly trained on biosafety and biosecurity issues. As a result, these officials have to make do with on the job training related to
these issues.\textsuperscript{169} It was suggested that a more standardized training program be required for these higher level positions in an effort to improve safety and security.\textsuperscript{170}

The results from the investigator survey echoed the feedback we received during in-person interviews on biosafety and biosecurity at VHA. As shown in Exhibit 52, most respondents were satisfied with the inspection, storage, recordkeeping, and disposal procedures, and access to reagents. However, 57% thought that the frequency of training was too high and about a third of the researchers did not think that environmental protection policies were appropriate or that the safety officer understands their needs.

**Exhibit 41. Satisfaction with policies and procedures related to biohazards and recordkeeping**

*Do you agree with the following statements?*

<table>
<thead>
<tr>
<th>Percent agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of training programs is too high</strong></td>
</tr>
<tr>
<td><strong>Quality of training programs is high</strong></td>
</tr>
<tr>
<td><strong>Safety Officer understands researcher needs</strong></td>
</tr>
<tr>
<td><strong>Disposal procedures are adequate</strong></td>
</tr>
<tr>
<td><strong>Waste storage procedures are adequate</strong></td>
</tr>
<tr>
<td><strong>Access to biological and chemical agents is adequate</strong></td>
</tr>
<tr>
<td><strong>Environmental protection policies are appropriate</strong></td>
</tr>
<tr>
<td><strong>Record keeping for hazardous agents is appropriate</strong></td>
</tr>
<tr>
<td><strong>Inspections of lab space are thorough</strong></td>
</tr>
</tbody>
</table>

*Source: Abt Associates.*

*Frequencies were calculated excluding respondents indicating N/A.*

*N=1,034.*

**Information Technology**

Prior to 2006, Information Technology (IT) services at the Veterans Benefits Administration (VBA), the National Cemeteries, and the Veterans Health Administration (VHA) were delivered independently. In 2006, a VA laptop computer containing information on 25 million Veterans was stolen from an

\textsuperscript{169} Interview #49. May 6, 2011.

\textsuperscript{170} Ibid.
employee’s home (the “Birmingham incident”). An outcry in the national press followed, causing considerable damage to VA’s image.\textsuperscript{171} (According to the interviews, no misuse of data actually occurred.) In addition, by then VA had earned a reputation for its inability to account for IT expenditures across the organization.\textsuperscript{172} We assume that this reputation, compounded by the Birmingham incident, resulted in the Congressional mandate to restructure IT support by creating a separate central organization with its own budget. The Office of Information and Technology (OI&T) was established.

According to a memorandum titled \textit{Organizational Adjustment to the Office of Information and Technology}, the goals of OI&T are to improve customer service, manage projects to an outcome, provide operational metrics, ensure information protection, and improve financial reporting. However, numerous interviews suggested to us that OI&T is not viewed by the research community as effective in these roles.

\textbf{Views on IT support services}

Adequacy of IT support was the subject of complaints by dozens of individuals we interviewed, including ACOS, center directors, ORD leadership, and ORD staff. We were told that the lack of IT support has worsened since the creation of OI&T and was a constant source of frustration. In the past, IT-related issues were resolved locally, and the centralization of IT led to additional paperwork requirements and project delays. The commonly expressed view was that OI&T staff did not understand the research environment or the needs of the community. Respondents said that it took many months to process a request for installing statistical software, and when installed it turned out to be an outdated version. In another case conveyed to us, OI&T was slow in providing loaner laptops for a peer review panel, and when the laptops came they did not contain the requisite software, and the computers had to be rented from a hotel. As the peer review process is a public event, this situation caused an embarrassment to the senior research leader at VA.

Researchers also complained that they were unable to use research funds, including extramural grants, to purchase the IT equipment and software that they needed for their projects. Instead, they had to submit a request through OI&T, which caused delays. Furthermore, the researchers did not necessarily receive the equipment that they wanted, because OI&T supplies only specific computer models and software licenses. For instance, the academic community prefers Macintosh computers, but OI&T does not provide these computers or support for them. An opinion was expressed that laptops and BlackBerries were difficult to obtain and these pieces of equipment were distributed to the field in an inequitable manner. Finally, interviewees reported challenges in connecting computers to the VA network, sharing data with the affiliates, and taking data to be presented at meetings (only specific encrypted thumb drives are permitted and these are not always available).

In order to understand the perspective of OI&T and the challenges in providing support to the research community, we interviewed a senior-level administrator at the organization. According to this person, OI&T had a difficult beginning: all but 5 of 70–80 IT employees at the time were laid off, and the CIO resigned.

OI&T pointed out several benefits of a centralized model of IT service delivery to ORD. Before the creation of OI&T, this person said, the emphasis of IT support was on health care, and research was seen

\textsuperscript{171} For example, USA Today May 2006. \textit{VA Computer Disk Stolen}.

\textsuperscript{172} Key informant interview.
as a low priority. Since the creation of OI&T, all branches of VA have been treated equally. Furthermore, OI&T has been channeling significant extra funds toward the research program: in addition to the $10 million allocated to ORD, OI&T is providing support for the genomic initiative, VINCI (Veterans' Informatics, Information and Computing Infrastructure),\(^\text{173}\) and RAMS (research administrative management system).\(^\text{174}\) Respondent also said that before OI&T, researchers were using outdated equipment, which since then has been replaced with newer models. While we do not have the documentation to verify some of these claims, ORD leadership did confirm that OI&T has provided additional support to the research program,\(^\text{175}\) and the VINCI website indicates that the initiative is a partnership between OI&T and ORD.\(^\text{176}\)

OI&T disputed the claim that they were slow in providing the necessary software and that the software they installed was out of date. Our informant noted that through the VINCI initiative OI&T is purchasing enterprise-level licenses, which are significantly cheaper than individual licenses that researchers request. We found that the VINCI website contains a list of applications that it hosts, including commonly used statistical software packages SAS, R, and SPSS. The website notes that these applications will run much faster through VINCI than through the local server.\(^\text{177}\) OI&T pointed out to us that IT funds, already limited, will likely decrease over time and that the best way to support growing IT needs of the research community is through centralization, because purchasing enterprise-level licenses and computer equipment in bulk is significantly more economical. When asked why researchers continue to be dissatisfied with OI&T, our informant said that the IT support has been inadequate for a long time (“the researchers are starved”) and that there was still room for improvement.

From the conversations with the field, we got an impression that there was no venue for resolving IT-related issues, and we asked OI&T what researchers should do if they cannot get what they need. Our respondent said that OI&T has set up a regional governance/communication system under which researchers who are dissatisfied with their local CIO should bring their requests to the VISN CIO, then to regional director, and finally to the OI&T/ORD Executive Partnership Council, which meets regularly to discuss topics such as the progress of IT projects, problems or incidents related to IT, and IT budget updates. OI&T staff said that 99.9% of cases are solved via this escalation process. This respondent was unsure whether the field is aware that they can resolve their problems via this mechanism and agreed that continual communication is necessary.

OI&T also questioned the claim that IT equipment cannot be purchased with research funds and that the organization does not support Macintosh computers. According to this person, research funds can be used to buy equipment and OI&T will connect this equipment to the VA network and will provide technical support. We were given an example of a researcher in California who built an extensive Macintosh-based computer system using a combination of VA and non-VA funds. Although the hardware platform for this system was not OI&T-approved, OI&T will support its maintenance using its own resources. Understanding that Macintosh computers are very popular with the research community, OI&T said that it has put together a team with limited support capability to assist Macintosh users.


\(^\text{174}\) Key informant interview.

\(^\text{175}\) Key informant interview.


The level of dissatisfaction expressed by the research community with IT support was higher than for any other research-related process at VA. Survey data were consistent with criticism expressed by ACOS and other interviewees about the quality of IT support, its timeliness, availability of equipment, and understanding of researcher needs. We found that in all areas of IT support less than half of respondents expressed satisfaction. Purchasing of IT software and hardware, linking of equipment to the VA network, ability to integrate VA and non-VA data, timeliness of support, and transportability of data emerged as especially problematic (Exhibit 42). Only 15% of researchers agreed with the statement that OI&T staff understand their needs and only 20% that OI&T supports their research. Most researchers do not have the tools to manage and analyze large-scale data and are having problems with remote access. Over a third of respondents reported that they were unable to initiate a project because of IT-related delays.

Exhibit 42. Satisfaction with IT services

<table>
<thead>
<tr>
<th>Area of IT support</th>
<th>Percent agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is easy to link equipment to the VA IT network</td>
<td>5</td>
</tr>
<tr>
<td>Policies and procedures for purchasing IT hardware and software meet your needs</td>
<td>10</td>
</tr>
<tr>
<td>You are satisfied with your ability to integrate VA and non-VA data</td>
<td>10</td>
</tr>
<tr>
<td>OI&amp;T staff understand the IT needs of VA researchers</td>
<td>15</td>
</tr>
<tr>
<td>It is easy to take data to presentations at meetings outside of VA</td>
<td>18</td>
</tr>
<tr>
<td>OI&amp;T supports your research program</td>
<td>20</td>
</tr>
<tr>
<td>Assistance from OI&amp;T is provided in a timely manner</td>
<td>21</td>
</tr>
<tr>
<td>You have IT tools that you need to manage and analyze large-scale data</td>
<td>22</td>
</tr>
<tr>
<td>OI&amp;T staff have been able to solve your IT problems</td>
<td>27</td>
</tr>
<tr>
<td>You are satisfied with remote access to VA computer network</td>
<td>28</td>
</tr>
<tr>
<td>Policies and procedures for accessing VA data for research meet your needs</td>
<td>29</td>
</tr>
<tr>
<td>You were unable to initiate a project because of IT-related delays</td>
<td>34</td>
</tr>
</tbody>
</table>

Source: Abt Associates Survey of VA Researchers.
N=1,034.

As we heard in the interviews that purchasing of IT equipment and software and other aspects of IT support were very slow, we asked respondents to estimate the duration of time that was necessary for various IT-related activities. We found that it took the vast majority of researchers at least a month to get what they needed and in many cases it took more than four months (Exhibit 43). Eleven percent of researchers said that it took more than a year to obtain and install software and 15% that it took more than a year to acquire IT-related equipment.
Exhibit 43. Duration of time to receive IT services and equipment

![Graph showing duration of time to receive IT services and equipment]

Source: Abt Associates survey of researchers.  
N=1,034.

**Personally Identifiable Information**

Personally Identifiable Information (PII) is defined as “any information which can be used to distinguish or trace an individual’s identity, such as their name, social security number, date and place of birth, mother’s maiden name, biometric records, or any information that is linked or linkable to an individual. Education, financial transactions, medical history, and criminal or employment history are included. Individually identifiable health information, protected health information, and privacy-protected information are also included in this category.” Handling of PII is governed by several federal laws and regulations, which include the Privacy Act of 1974, Health Insurance Portability and Accountability Act (HIPAA), and Federal Information Security Management Act (FISMA).

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178 Any information maintained by VHA that identifies the individual and, except for individually identifiable health information, is retrieved by the individual’s name or other unique identifier.

179 Privacy-protected information encompasses personally identifiable information, individually identifiable information, and protected health information.

180 Handbook 6500.

181 The Act governs the “collection, maintenance, use, and dissemination of personally identifiable information about individuals that is maintained in systems of records by federal agencies.” Public Law No. 93-579.

182 HIPPA stipulates how to safeguard medical information and protect the privacy of a patient, while allowing clinicians to share and have access to health data for the purpose of treating a patient. Any clinician or researcher who has access to medical information must understand and comply with HIPAA rules. www.cms.org/ocr/hipaa.
In the interviews, we were told that the level of data protection at VA was disproportionate to the data’s sensitivity. To examine whether this view was widely held, we explored this issue in the survey. We found that 43% of respondents did not agree with the statement “IT standards for data protection are appropriate for the level of data sensitivity” versus 33% who agreed (Exhibit 44).

**Exhibit 44. Perception of the appropriateness of data security**

*Do you agree that IT standards of data protection are appropriate for the level of data security?*

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>23</td>
<td>20</td>
<td>18</td>
<td>27</td>
<td>7</td>
<td>4</td>
</tr>
</tbody>
</table>

Source: Abt Associates survey of researchers.
N=1,034.

The nature of the question about PII posed to us by VA suggests that researchers might be held to a different standard when it comes to protecting PII than staff at other branches of VA (for instance at the Veterans’ benefits office). Researchers were asked in the survey whether this was the case. Survey data showed that 55% of respondents believed that the standards for protecting PII were applied more rigorously to them than to health care providers (Exhibit 45). Open-ended comments have not been analyzed to further understand the reason for and the nature of this difference. These data will be presented in subsequent report drafts.

183 FISMA is a government-wide security standard which specifies standards for categorizing information systems and security controls.
Credentialing

The goal of credentialing in the context of a health care setting is to verify the provider’s legitimacy and qualifications in order to protect the patients. The Veterans Health Administration (VHA) defines credentialing as the “systematic process of screening and evaluating qualifications and other credentials, including licensure, registration, certification, education, training, experience, and current competence.”

Credentialing practice at VA has been shaped by at least two widely publicized malpractice incidents which are worth a brief mention. In 1999, Paul Kornak, a physician with a revoked medical license, was hired as a research assistant at Stratton VA Medical Center in Albany, NY. Kornak had attended medical school in Poland and claimed during the interview with VA that this was the reason why his license had been revoked. As it turned out, he had forged his medical credentials. Kornak was responsible for recruitment and data collection for several pharmaceutical research studies involving VA cancer patients. In this role, Kornak allegedly falsified data in patient medical records in order to enroll participants who should have been disqualified for medical reasons. Investigation by the Food and Drug Administration uncovered serious errors that occurred during the study, including omission of tests, incorrect medication dosage, and prescription of incompatible medications. At least five deaths were linked to the trials.

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In response to this incident, the General Accounting Office (GAO) launched a probe into VA hiring practices. GAO concluded that physicians and dentists, who were required to undergo background checks in a national database of disciplinary actions containing records of criminal convictions, were adequately credentialed. This background check was not applied to other medical staff, such as nurses and therapists, even though the database included information on all licensed practitioners. Finally, many practitioners with direct patient access, for example medical residents, were not required to undergo fingerprinting or background investigations.

GAO also examined compliance with credentialing policies at four VA facilities and got mixed results. The examiners concluded that while the facilities were reasonably diligent in verifying credentials for continued employment, investigations of new staff were less thorough. At one facility, for example, VA neglected to review the results of completed background investigations for new hires for over a year. GAO also noted that while the Central Office was responsible for credentialing oversight, no policy guidance or resources had been provided to the office to support these activities. The GAO report did not directly address researcher credentialing, even though the probe was spurred by an incident involving a researcher.

In 2007 a patient bled to death following gall bladder surgery performed at the Marion VA Medical Center and an additional 10 patients were found to have died as a result of inadequate medical care at this facility. It later emerged that before being hired by VA, the surgeon performing the operation had made payments in two malpractice suits in Massachusetts, but that VA was unaware of these serious problems at the time of hire. In defense of VA, the acting director of the Marion Medical Center argued that the facility appropriately followed VA credentialing procedures, which included verification of licenses in other states and checking malpractice claims contained in the National Practitioner Data Bank. However, senators Obama and Durbin of Illinois responded that a cursory check of publicly available information would have quickly raised red flags about the surgeon. An investigation by the VA Office of Inspector General following this incident identified deficiencies in credentialing and privileging of physicians and in the monitoring of surgeons at the Marion facility. In response, VA reviewed the credentials of 17,000 health care providers across the country.


190 Ibid.


Because of the incident at the Marion VA Center, Congress mandated a more stringent credentialing process at VA in the Veterans’ Health Care Authorization Act of 2009.\(^{193}\) Physicians were required to disclose malpractice claims and to authorize their state licensing boards to release records to VA; all VA employees had to resubmit credential information every two years.\(^{194}\)

**Researcher credentialing at VA**

Credentialing must be completed before a new hire’s duties begin, regardless of his/her compensation and full-time/part-time status.\(^{195}\) The document entitled *Requirement for credentialing of all research staff* describes who must be credentialed through the VA system called VetPro:

- “All health care professionals who claim licensure, certification or registration as applicable to their position within VHA.
- All research staff that holds a degree that may make them eligible for licensure, registration, or certification. Such persons would include but is not limited to: nurses, physicians, Clinical Psychologists, and pharmacists that do not have a current active license.
- All research staff including research administrative personnel, who by the nature of their position have the potential to assume patient care-related duties, or oversee the quality or safety of the patient care delivered, e.g. Research Assistants, Project Officers, etc.”\(^{196}\)

VetPro is an Internet-enabled data system developed at VA in 1997 in collaboration with the Department of Health and Human Services to facilitate sharing of credentialing information.\(^{197,198}\) To initiate the credentialing process, the applicants enter various data elements, including all licenses they have held with issue/expiration dates, certifications by professional organizations, education, and professional references.\(^{199}\) In addition, the applicants are presented with several yes/no questions on topics such as a history of malpractice accusations. After the applicant has completed VetPro, a VA credentialer verifies the information, submitting corrections when it conflicts with the credentialer’s source (Exhibit 46). To verify foreign degrees, VA must make two requests to the degree granting institutions, waiting one month for a response between each request, before proceeding to the next step in the credentialing process.\(^{200}\)

\(^{194}\) Ibid. \\
\(^{195}\) Requirement for credentialing of all research staff. May 10, 2007. \\
\(^{196}\) Ibid. \\
\(^{198}\) Within a few years, VetPro was adopted by the Immigration and Naturalization Service, the National Aeronautics and Space Administration, the National Health Service Corps, and the Office of Emergency Preparedness, among others. In 2002, it was recognized as one of the most innovative information systems in e-government. \\
\(^{200}\) Interview #56. January 2011.
Once credentialing is complete, the new hire’s supervisor develops a Research Scope of Practice (SOP) statement, which delineates his/her duties. Researchers with clinical privileges do not need a detailed clinical SOP statement, because it is issued by the facility at which they have privileges.\textsuperscript{201}

The facility director and the ACOS for R&D are responsible for ensuring that all researchers are appropriately credentialed. The ACOS for R&D at each facility is also responsible for developing and updating a tracking system that records staff compliance with VHA Directive 2009-054, including clearance through VetPro and completion of SOP statements.

A number of credentialing challenges have been documented in the literature. For example, unexplained gaps in an applicant’s curriculum vitae can be difficulty to verify, in particular when former employers or malpractice insurance carriers change names, move, or go out of business.\textsuperscript{202} The credentialing process is time-consuming, leading to hiring delays. Language barriers and poor recordkeeping are obstacles to verifying credentials of researchers trained outside of the US.\textsuperscript{203}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{201} VHA Directive 2009-054. “Credentialing of unlicensed research staff.” Veterans Health Administration. Washington, D.C., 2009.
\item \textsuperscript{202} Gilchrist, G. “Barriers and obstacles in the credentialing and privileging process.” CRICO/RMF Forum 24 (2006).
\item \textsuperscript{203} Interview #12. February 2011.
\end{itemize}
\end{footnotesize}
Research community views

To determine whether the credentialing process meets the needs of the VA research community, we asked questions about credentialing in interviews and in the researcher survey. With one exception, all interview subjects expressed frustration with the credentialing process. We heard that hiring could take as long as nine months, that VetPro was time-consuming and onerous, and that the credentialing process significantly slowed the progress of research. Respondents said that even medical students and residents at affiliate institutions conducting research at VA had to go through a lengthy credentialing process. In some cases the administrative burden and hiring delays discouraged students from getting involved in research at the VAMCs.

The prevailing view, expressed by the research community and by some ORD staff, was that the level of scrutiny currently in place at VA is disproportionate to the level of risk. Several ACOS appeared frustrated by the requirement that even researchers who would have no access to human subjects were

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204 Interview #30. April 2011.

205 Interview #46. April 2011.
nevertheless required to go through VetPro, seemingly in order to verify the degrees that were irrelevant to their duties. Respondents felt strongly that students and residents in the accredited affiliate programs, basic researchers, and clinical staff without patient care-related duties should be exempt from VetPro credentialing.

We also heard an opinion that responsibility for credentialing should not lie with ACOS and/or with the medical center. Finally, we were told that HR departments have little or no experience with research, do not understand the needs of researchers, and make arbitrary hiring and credentialing decisions. Only 1 of 10 ACOS interviewed appeared to be satisfied with the credentialing and hiring processes.

To collect information related to the hiring process more systematically and on a larger scale, we included a few questions in the survey of VA researchers. One of the questions was related to the duration of time to obtain credentials for a new researcher not involved in clinical duties. Exhibit 47 shows that 11% of the researchers had to wait less than a month, 41% from 1–3 months, and 23% more than 4 months to receive the credentials.

Exhibit 47. Average time to obtain credentials for a researcher not involved in patient care

<table>
<thead>
<tr>
<th>Duration</th>
<th>Percent respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month</td>
<td>11</td>
</tr>
<tr>
<td>1-3 months</td>
<td>41</td>
</tr>
<tr>
<td>4-6 months</td>
<td>17</td>
</tr>
<tr>
<td>7-9 months</td>
<td>4</td>
</tr>
<tr>
<td>10-12 months</td>
<td>1</td>
</tr>
<tr>
<td>&gt;12 months</td>
<td>1</td>
</tr>
<tr>
<td>NA</td>
<td>23</td>
</tr>
</tbody>
</table>

Source: Abt Associates. Survey of VA researchers. Individuals responding not applicable were excluded from the counts.

N=1,034.

In the survey, we also explored the level of satisfaction with credentialing in the research community. We found that 38% of respondents disagreed or strongly disagreed with the statement that credentialing requirements are appropriate (Exhibit 48).

For example, interview #12. February 11, 2011.

Interview #15. February 2011.

Interview #21. March 10, 2011; Interview #17, March 1, 2011.

Interview #17. March 1, 2011.

Interview #18. March 1, 2011.
Exhibit 48. Satisfaction with VA credentialing requirements

*Indicate your level of agreement with the following statement: “VA credentialing requirements for research (e.g. VetPro) are appropriate”*

<table>
<thead>
<tr>
<th>Level</th>
<th>Percent Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>8</td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>3</td>
</tr>
<tr>
<td>Agree</td>
<td>27</td>
</tr>
<tr>
<td>Neutral</td>
<td>26</td>
</tr>
<tr>
<td>Disagree</td>
<td>22</td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>16</td>
</tr>
</tbody>
</table>

*Source: Abt Associates. Survey of VA researchers. N=1,034*

**Communication**

Effective communication is instrumental to the success of the VA research program. Because the primary mission of VA and its research program is to serve the health care needs of Veterans, program leadership must effectively convey the benefits of the research to the Veterans, organizations representing Veterans’ interests, and Congress, which controls much of the funding for research. In the US, NIH is the major funder of biomedical research, with a budget that is orders of magnitude larger than what is appropriated for VA research. Thus, ORD leadership must communicate to its stakeholders in what way the program is different from NIH.

VA research is conducted by approximately 2,000 VA-funded investigators and by several thousand additional investigators who receive funding from other entities including NIH, DOD, and industry at over 100 VA medical centers (VAMCs) across the country. ORD leadership needs to have a channel to communicate with this large and diffuse community. In addition, most VAMCs have important relationships with local universities, adding another level of complexity to communication and governance. Finally, the VA research program is uniquely embedded in the health care system, and to be effective in serving the Veterans, VA scientists and program leadership must develop and sustain ties to the operations branch of VA.

Many of the informants interviewed stated that the research program has taken great strides to reach stakeholders who support research or are affected by research results. In this section, we describe our findings of VA communication activities.

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211 Interview #6, January 25, 2011
Communication-related policies

Policies related to research communication are described in a VHA Handbooks: *Presentation of Research Results* (1200.19). This Handbook encourages researchers to share scientific, technical, and medical information at professional meetings and through publications, and instructs them on how to include acknowledgements and disclaimers. Articles and presentations by VA researchers must acknowledge their funding service (BLR&D, HSR&D, CSR&D or RR&D), and specify the site where the research was performed (name of medical center) and the title of the VA investigator. According to the Handbook, failure to acknowledge VA carries serious penalties, including possible discontinuation of funding and/or revocation of privileges to conduct research at VA. We understand that this requirement is not enforced.

Another resource for communication-related guidance is VHA Handbook 1203.05, which discusses publication and review policies for the *Journal of Rehabilitation Research and Development (JRRD)*, the VA trade journal. JRRD is a peer-reviewed, open-access technical journal which publishes articles in rehabilitation research. The stated goal of the Journal is to “enhance the quality and relevance of VA rehabilitation research and to disseminate biomedical and engineering advances.” JRRD is issued 10 times a year and is open to both VA and non-VA research community. The JRRD Handbook includes instructions to authors, printing technical specifications, and descriptions of roles and responsibilities of the editorial board.212

Communication Office initiatives

ORD has a Communication Office with a staff of seven full-time equivalents.213 In 2007, under the direction of the current CRADO, the Office launched a multi-year initiative to improve external (between VA and the outside world) and internal (within-VA) communications. The goals of the initiative were to convey to the Veterans and to other stakeholders the value and quality of the research program, to highlight cutting-edge medical treatments available to Veterans, to develop consistent message and brand, and to facilitate information exchange between the Central Office, the field, and VHA and VA leadership.

The internal communication initiative spans two phases.214 In Phase I, the Communications Office developed resources to refine and reinforce the program focus. These resources included core messages, research competencies, presentation templates, fact sheets, talking points, and a photo archive. In Phase II, which is underway, a SharePoint tool is being used to facilitate the exchange of information and to reduce duplication and inconsistencies in the dissemination of information. Phase I of the internal communication project has been completed and Phase II is scheduled to be completed in September 2011.

The external communication initiative, which is being carried out in parallel, includes four phases. In the first phase, which began in 2007, ORD communications team collaborated with its VA partners to define the “desired outcome, target, consumer orientation, competing factors, behavior goals, audience segments,” and correspondingly, most appropriate communication strategies (a social marketing approach was ultimately selected). The result of the phase was the development of an “outward

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212 VHA Handbook 1203.05, *Journal of Rehabilitation and Research Development*.

213 Key informant interview #5, January 25, 2011.

214 ORD Communication Office Communication Initiative Plan.
focused core message, uniform VA R&D program identification mark, and external communication materials." These resources were piloted for a year to ascertain their effectiveness, prior to the national rollout in Phase II (January 2009–April 2010). During this phase, the tools were refined and expanded. In Phase III (April 2010–September 2011), the Office began to develop dissemination strategies to Veteran service organizations (VSOs), academic partners, the scientific community, and the media, along with continued efforts to provide the field with various communication tools. The initiative is currently in its fourth phase, which includes an evaluation of all components and final revisions, and is scheduled for completion in September 2011.

**Communication vehicles currently used by ORD**

ORD’s Communications Office aims to provide access to information that is commensurate with various users’ preferences. Researchers in the field, for instance, represent a highly educated group with easy access to the Internet. In contrast, the level of computer access and skill varies greatly among Veterans. Younger Veterans are likely to be technologically savvy and probably use the Internet to obtain information, while older Veterans might prefer brief pamphlets or other printed media. According to ORD’s communications staff, they strive to reach out to all these groups using the methods that would be most accessible to them. These tools and methods are described in the following paragraphs.

**SharePoint.** The communications staff is setting up a number of different tools to exchange information internally, with an expectation that these tools will help transmit the core message of the research program – its value to Veterans and the general population. One of these tools is SharePoint, an internal communication portal, which will contain a variety of resources such as investigator profiles, content expert lists, common calendars, issue briefs, a photo bank, a document archive (including publications), templates, event notifications, meeting summaries, the strategic plan, and an early-alert communication system. SharePoint will also feature regular communications from ORD leadership.

The SharePoint tool was not yet fully operational at the time of writing this report, but the Office of Communications provided us with several screen shots illustrating its various components. One of these screen shots is shown in Exhibit 49. This web page contains the address from Dr. Kupersmith about VA research in women’s health and links to VA news releases and VHA announcements.

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215 Key informant interview #14, Feb 28, 2011.
ORD website. ORD has its own website, which can be found at http://www.research.va.gov/. According to ORD staff, the website is one of the most effective ways to communicate with the outside world. This view is supported by data, as the site receives approximately four million visits per year. The site serves as a central repository of information for internal and external audiences. It provides an overview of ORD’s mission, organizational structure, and programs, and communicates the latest news. A VA researcher visiting the site might learn about the processes of proposal submission and peer review, and find various handbooks and other policy documents that govern research activities at VHA. Funding opportunities are also published, but only on the Intranet version, as VA is an intramural funding agency only. A Veteran visiting the public web site can get information about participation in research by following the “for Veterans” link, where they can locate research centers and clinical trials in their area (Exhibit 50).

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Data provided by Communications Office.
According to the Communications Office, one of the most popular sections of the ORD website is the News & Video section, which features current research highlights, announcements, press releases, and upcoming events. For example, at the time of writing the site featured the national launch of the Million Veterans Program. The website receives approximately 200,000 requests for downloads of electronic documents annually, including past and current editions of VA publications and clinical brochures (Exhibit 51).
Videos posted on the ORD website are also available on YouTube, a popular video download site. These videos are intended as an educational tool about various diseases and conditions and about research efforts to improve the treatment of Veterans who suffer from them. Some of the videos include common conditions afflicting Veterans, including traumatic brain injury, post-traumatic stress disorder, spinal cord injury, cancer, cardiovascular disease/stroke, and pain management. Based on the data provided by the Communications Office, the ORD YouTube website is visited by individuals from every state and from other countries including India, the United Kingdom, Thailand, Lebanon, Japan, and China (data not shown).

In addition to passive dissemination of information via the website, ORD utilizes a direct messaging strategy: the Communications Office electronically distributes the ORD newsletter called Research Currents as well as event notices to approximately 5,500 individuals. ORD also takes advantage of social media via Facebook and Twitter to reach out to its most "connected" audience.

Printed resources. The main ORD publication is Research Currents, a relatively short newsletter intended for a broad audience. The May–June 2011 issue of Research Currents, for instance, includes a story about Dr. Watson, a powerful IBM computer that is being tested by VA researchers as a tool to analyze medical information. The issue also contains a story about a combat Veteran turned VA researcher and the description of research results suggesting that a compound derived from nicotine may have protective properties against Alzheimer’s disease. Research Currents can be downloaded from the ORD website and is electronically distributed or mailed to VHA employees, Veterans, and other readers; printed copies are available throughout VA medical centers.

In addition to Research Currents, ORD publishes dozens of brochures on various medical topics that are the subject of VA research. These topics include PTSD, TBI, prosthetics, rural health, and women's health. The purpose of the brochures is to educate Veterans and their families about the subject and to
explain what the VA research community is doing to identify or advance treatments. ORD publishes VA Research Today, a scientific journal which features current research advances, and gives talks to the Veteran service organizations once a year.

**Research Week.** Research Week is an annual event dedicated to communicating the benefits of research and to celebrating the research program. It is also a vehicle to strengthen the relationship between VA and its partners, especially VSOs. ORD hosts the event in Washington, DC and individual VAMCs host local events across the country. VSOs and other ORD partners are closely involved in the planning of the event (for instance in choosing speakers) and they sponsor some of the activities.

The most recent Research Week in Washington, held in May 2011, was attended by some members of the study team. The events included an after-hours Congressional reception (hosted by VA partners) and a half-day session at the VA headquarters. During the session, presentations on scientific advances funded by the four Services and impassioned testimonies from several Veterans about personal benefits of research were given. The session even included trivia games with a VA research theme. Following the sessions, visitors could browse posters from VA researchers. Similar events took place across the country. Some medical centers also gave tours of their research facilities and one center hosted a ribbon cutting ceremony for its newly constructed research building.

**Ad hoc outreach by the field.** In addition to formal communication efforts spearheaded by the Communications Office, we learned that individual medical centers have their own outreach activities. One ACOS said that his facility collaborated with VSOs to ensure that Veterans learn about ORD research and its potential for new treatments. Additionally, some facilities try to publish a certain number of press releases per year, with the help from the local VA Public Affairs office.

**Internal communication.** To improve communicate with the field, a few years ago VHA established the Field Research Advisory Committee (FRAC). The mission of FRAC is to promote communication between ORD and investigators in the field, to provide input on issues relevant to VA research, and to participate in strategic planning. FRAC meets on a quarterly basis, and meeting minutes are distributed to the field. FRAC membership includes representatives from the field and the Central Office; the field members are elected for 3-year terms, with one-third rotating off annually. The research community is represented on FRAC by five ACOS, one from each geographical region; researchers from the Centres of Excellence and Cooperative Studies Program; and career scientists. On behalf of ORD, FRAC is staffed by the CRADO, Deputy CRADO, and four Service Directors. Another form of communication between the Central Office and the ACOS is a monthly call hosted by ORD.

**Communication challenges faced by ORD staff**

In the interviews, ORD communication staff mentioned some of the challenges which prevent them from functioning at full potential. One challenge was lack of staff; the office tries to compensate for staffing shortages by hiring people with non-overlapping and diverse skill sets. Another challenge was inadequate IT support, especially for Macintosh computers. These computers were described as essential for the activities of the Office and yet communications staff was unable to procure them and had to book studio time for developing videos and visual graphics. Having to rent computers and space was both expensive and inconvenient; in fact, interviewees noted that their renting expenditures per month were higher than the cost of a new Macintosh computer.
All national press releases must be routed through the Office of Public Affairs (OPA) for approval. We heard that the requirement for OPA approval causes significant delays in getting press releases cleared for media distribution, and by the time the clearance is obtained the story may be too old to be newsworthy. According to communications staff, long delays discourage reporters from approaching ORD for comment on the news story.

**Communication between ORD and Congress**

Although communication between ORD and Congress was not examined in detail, anecdotal evidence suggests that ORD leaders visit the Capitol Hill. Congressional staffers were present at the reception and at presentations during the May 2011 Research Week, also suggesting that there is a relationship between ORD and Congress.

**Research community views on communication**

We discussed internal communication at VA with ACOS and center directors and included a few questions on this topic in the survey of VA researchers. ACOS said that the utility of FRAC depended on the representing member. Some ACOS reported that their FRAC member was very active and engaged, while others were not in touch with their representative or even know who that individual was.

It emerged from the interviews that ACOS did not see monthly calls with ORD as a successful communication venue. While the goal of the call is to improve communication with the field, some ACOS expressed the view that it was mainly a mechanism to convey policy changes and new requirements from ORD. ACOS said that they did not feel comfortable asking tough questions or sharing problems faced by their communities. A view was expressed that ORD could use these calls to get input on draft policies from ACOS instead of establishing these policies without any input from the field.

Respondents were asked whether the research program was well known outside of VA. The answers were mixed. Some individuals – including distinguished NRAC members and senior academic administrators – were confident that the program was widely known and respected in the research community. Others noted that more could be done. Several interviewees believed that VA has not traditionally taken full credit for its important research contributions. The development of the nicotine patch was often given as an example of a missed opportunity on the part of VA to get the recognition its research program deserved.

A few questions related to communication were posed to the research community. We found that 47% and 57% of respondents agreed or strongly agreed, respectively, that research findings are effectively communicated within and outside of VA (Exhibit 52). In contrast, only 15% thought that communication of research to Veterans was effective.

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217 Key informant interview #14, February 28, 2011.
Exhibit 52. Perceived effectiveness of communication of research findings

To what extent do you agree with the following statements?

<table>
<thead>
<tr>
<th>N/A</th>
<th>Strongly agree/agree</th>
<th>Neutral</th>
<th>Strongly disagree/disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Research findings are effectively communicated to veterans or VSOs
- 6 Strongly agree/agree
- 15 Neutral
- 44 Strongly disagree/disagree

Research findings are effectively communicated outside of VA
- 1 Strongly agree/agree
- 26 Neutral
- 57 Strongly disagree/disagree

Research findings are effectively communicated within VA
- 1 Strongly agree/agree
- 31 Neutral
- 47 Strongly disagree/disagree

Source: Abt Associates.
N=1,034.

Commercialization

Commercialization of inventions emerging from VA research (the process called “technology transfer”) is a necessary step for implementing research ideas in clinical practice. We examined the structures and mechanisms that govern technology transfer at VA as well as the volume of invention disclosures, patents, and licenses emerging from the research program. Data presented here are based on the interviews with ORD staff, examination of the ORD website, and analyses of data provided by the technology transfer office.

Technology transfer activities at ORD are carried out by the Technology Transfer Program (TTP). The mission of the program is to “serve the American public by translating the results of worthy discoveries made by employees of VA into practice.” The TTP was created in 2000, following NRAC recommendation, and currently accomplishes its mission by educating the research community about intellectual property, evaluating and commercializing inventions, and asserting ownership interest, if necessary. It was initially established under the Rehabilitation Service with the Service director as manager. Now part of ORD, TTP employs eight staff including three technology transfer specialists each responsible for a particular geographical area. TPP staff review the disclosure packages submitted by

219 Key informant interview (December 2010).
220 http://www.research.va.gov/programs/tech_transfer/default.cfm (April 2011) and key informant interview (December 2010).
facilities and make ownership recommendations to the Office of General Council, which makes the final determinations on how to proceed with the inventions.

**Inventions jointly owned with academic affiliates**

Because many PIs at VA have academic affiliations, the affiliate universities can often claim ownership of the invention along with VA. To help manage these situations, TTP developed the Cooperative Technology Administration Agreement (CTAA). According to the CTAA, universities have the first right to a patent and VA will take the lead on commercializing the invention only if the university chooses not to file for a patent. Regardless of the university disposition regarding the patent, VA retains ownership rights to the invention and any resulting royalties are divided between VA and the affiliate. Currently, VA has 59 active CTAs.

This arrangement is rooted in history. Until TTP became established, ORD did not have the expertise or the staff to commercialize inventions and all technology transfer activities were handled by the affiliates. As its technology transfer program matured, VA attempted to be more assertive about its intellectual property rights, but this attempt was met with staunch resistance from the affiliates, including lobbying Congress. In addition, TTP staff expressed the view that many researchers’ first loyalty is to the affiliate university and that they do not disclose all of their inventions to VA. TTP receives approximately 200 disclosures per year, but our informant estimates that the number of inventions is much higher.

**Inventions jointly owned with industry**

In some cases, VA research is funded or co-funded by industry and the industry sponsor will have a claim to the resulting invention. The Cooperative Research and Development Agreement (CRADA) governs the VA-industry relationship related to intellectual property. The Agreement states that any invention made by VA is jointly owned with the company. If the invention is made solely by VA, the company has the right of first refusal to license the invention from VA. There are currently 897 active CRADAs at VA, including with large biotechnology and pharmaceutical companies such as Amgen, AstraZeneca Pharmaceuticals, Bayer HealthCare Pharmaceuticals Inc, Bristol-Meyer Squibb, Eli Lilly, Genentech, Hoffmann-La Roche Inc, Merck & Co Inc, Novartis Pharmaceuticals Corporation, and Pfizer.

**Commercialization process at VA**

VA researchers are required to disclose any invention to ORD. The guidance to the researchers on what constitutes an invention and how to handle intellectual property is described in VHA Handbook 1200.18. Briefly, VA owns the invention if it has made “significant contribution” to its development; funding for research, facilities, materials, equipment, and employee time are all examples of significant contribution. If an invention (or believed invention) was made, the investigator is instructed to provide to his/her supervisor a statement containing description of the invention and the circumstances under

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221 Key informant interview (December 2010) and TTP Data Report 3-9-2011.
222 TTP Data Report 3-9-2011.
223 TTP Data Report 3-9-2011.
224 Key informant interview (December 2010).
which the invention was made, including the nature of VA’s contribution. Once reviewed by the investigator’s supervisor, the statement is submitted to the Research and Development Office and then to TTP.

TPP has a contract with a marketing firm, which advises the office on whether the product would have commercial value and/or would benefit Veterans. For example, an improved wheelchair is an example of a product that might not have a large market share, but would be valuable to Veterans. If the firm makes a positive decision, VA uses one of the 12 law firms on retainer to patent the invention (the choice of the firm is determined by the nature of the product). By law the inventor is entitled to royalties resulting from the invention. At VA, the inventor receives the first $2,000 and 40% of any additional royalties. Of the remaining, 10% goes to TTP and the rest is transferred to the facility where invention was made.

**Technology transfer outputs resulting from VA research**

Exhibit 53 shows the trend in the number of invention disclosures, patents, and licenses from the establishment of TTP to 2010. The number of invention disclosures and patents appears to have peaked in 2004, but declined somewhat since then (Exhibit 53A and B). Because the research program has extensive ties to universities, it was not surprising that most invention disclosures involved joint ownership (Exhibit 53A). The number of licenses increased dramatically over 10 years, from 3 in 2000 to 169 in 2010 (Exhibit 53C).

**Exhibit 53. Technology transfer products at VA**

A. Invention disclosures
Challenges reported by TTP staff

TTP program staff shared with us two challenges to the effective implementation of technology transfer. First, many universities lost their technology transfer specialists due to the recession. Because VA can start the patenting process only after the affiliate decides not to apply for a patent, many cases linger at the universities awaiting resolution. As example, a respondent cited a backlog of 150–200 inventions at a major university. VA cannot take any action until the university makes the decision not to pursue commercialization.

Another problem mentioned by TTP was insufficient staffing to handle the volume of invention disclosures. The respondent pointed out that the Department of Agriculture, which is similar in size to

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226 Key informant interview (December 2010).
VA, employs 24 technology transfer staff, while VA employs 8. TTP believes that with additional staff the Program would be able to increase patent revenue for VA. Last year, the revenue resulting from VA inventions was approximately $300,000.

Conflicts of Interest Policies

According to ORD, the definition of conflict of interest is as follows:

“An employee has a conflict of interest when he or she participates personally and substantially through decision, recommendation, giving advice, or other action, in any contract, case, controversy, or other particular matter knowing that he, his spouse, minor child, outside employer or certain others to which he or she has connection, has a financial interest in the matter. In research, such a conflict of interest would affect, potentially affect, or create the appearance that it could affect, the design, review, conduct, result or the reporting of research activities or findings.”

In February 1, 2005, VA rescinded Handbook 1200.13 titled Financial Conflict of Interest in Research, and since then VA has not had a separate policy or guidance for researchers. Instead, VA determined that any person involved in VA-approved research must abide by federal criminal conflict of interest standards and the Standards of Ethical Conduct for Executive Branch Employees. These standards are established by Office of Government Ethics and define ethical behaviors expected of federal employees. For example the standards prohibit any employee from giving or receiving contributions and from acquiring or holding certain financial interests. At VA, these standards also apply for Without Compensation appointments.

Conflicts of interest may occur among members of VA merit review committees. ORD follows the same conflicts of interest policies as NIH: individuals are expected to avoid participating in a matter if they are (a) based at the same institution as an applicant; (b) are requested by the applicants to be excluded; or (c) if the reviewer believes that he/she has a conflict. All reviewers must disclose any conflict of interest, real or apparent, to the Portfolio Manager (individual overseeing the review). If VA determines that a conflict of interest exists, the reviewer may not be involved in the review of that particular proposal.

Perspectives of VA Researchers on Key Organizational Issues

Do VA researchers have what they need to achieve a high level of performance? To examine the views of the research community, we conducted an on-line survey of all VA-funded PIs, all research CoE and REAP directors, and all CSP site investigators. Of 1,907 researchers in this group we received survey data from 1,034 (54%). Due to time limitations we report only high-level quantitative data for this draft. This chapter will be expanded with open-ended comments and updated with the final survey numbers. We will also analyze the answers by age, number of years at VA, gender, Service, and other variables to identify any important differences in these subgroups’ experiences.

227 VA Handbook 1200.13 Financial Conflict of Interest in Research.


229 Part 2635 - Standards for Ethical Conduct for Employees of the Executive Branch.

230 Key informant interview.

231 VA ORD Memorandum, Financial Conflict of Interest.
Exhibit 54 shows program areas for which more than half of all respondents expressed dissatisfaction or strong dissatisfaction. These included:

- Regulatory burden (amount of time spent on compliance and training)
- Inadequate funding support (for research and travel)
- Inadequate IT support (equipment purchasing, connectivity to non-VA sources, access to data, timeliness of support, use of data outside of VA)
- Inadequate Human resources support (hiring, attainment of WoC appointments, attainment of access to facilities).

**Exhibit 54. Areas of need that emerged from the survey**

<table>
<thead>
<tr>
<th>Area</th>
<th>Respondents indicating dissatisfaction or strong dissatisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of time spent on research compliance</td>
<td>69%</td>
</tr>
<tr>
<td>Amount of time spent on required training for research</td>
<td>57%</td>
</tr>
<tr>
<td>Levels of ORD funding for research</td>
<td>59%</td>
</tr>
<tr>
<td>Availability of travel funds</td>
<td>54%</td>
</tr>
<tr>
<td>Frequency of human subjects protection-related training</td>
<td>59%</td>
</tr>
<tr>
<td>Policies and procedures for purchasing IT equipment</td>
<td>72%</td>
</tr>
<tr>
<td>OI&amp;T staff understanding of research needs</td>
<td>65%</td>
</tr>
<tr>
<td>OI&amp;T support for research program</td>
<td>52%</td>
</tr>
<tr>
<td>Timeliness of IT support</td>
<td>52%</td>
</tr>
<tr>
<td>Ability to integrate VA and non-VA data</td>
<td>53%</td>
</tr>
<tr>
<td>Ability to take data to presentations outside of VA</td>
<td>60%</td>
</tr>
<tr>
<td>Ability to link equipment to VA network</td>
<td>72%</td>
</tr>
<tr>
<td>HR hiring policies</td>
<td>71%</td>
</tr>
<tr>
<td>Length of time to obtain WoC appointments</td>
<td>66%</td>
</tr>
<tr>
<td>Length of time to obtain access to VA facilities for students/interns</td>
<td>58%</td>
</tr>
</tbody>
</table>

N=1,034.

As it became clear early on in the evaluation that delays in obtaining products and services required for research were widespread at VA, we designed the survey to measure time to completion for several important research-related processes. Exhibit 55 shows the results. In the survey 12% and 15% of researchers indicated that it took longer than 10 months to receive a computer and scientific software,
respectively, and 19% that it took longer than 10 months to hire a researcher. A substantial number of researchers reported that acquiring non-IT equipment and executing a contract to purchase equipment or services was also very slow.

**Exhibit 55. Percent respondents indicating the length of time to complete research-related processes**

<table>
<thead>
<tr>
<th>Activity</th>
<th>0–3 months</th>
<th>4–9 months</th>
<th>10+ months</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtaining R&amp;D committee approval to submit a proposal</td>
<td>84%</td>
<td>8%</td>
<td>2%</td>
<td>6%</td>
</tr>
<tr>
<td>ORD review process</td>
<td>46%</td>
<td>43%</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Obtaining IRB approval for new study</td>
<td>58%</td>
<td>25%</td>
<td>3%</td>
<td>15%</td>
</tr>
<tr>
<td>Obtaining approval for animal use</td>
<td>31%</td>
<td>6%</td>
<td>1%</td>
<td>62%</td>
</tr>
<tr>
<td>Obtaining approval for use of isotopes</td>
<td>17%</td>
<td>1%</td>
<td>0%</td>
<td>82%</td>
</tr>
<tr>
<td>Obtaining approval to use hazardous agents</td>
<td>31%</td>
<td>3%</td>
<td>1%</td>
<td>66%</td>
</tr>
<tr>
<td>Obtaining credentials for new researcher</td>
<td>51%</td>
<td>21%</td>
<td>3%</td>
<td>24%</td>
</tr>
<tr>
<td>Obtaining WoC appointment for new researcher</td>
<td>56%</td>
<td>27%</td>
<td>4%</td>
<td>13%</td>
</tr>
<tr>
<td>Obtaining access to facility for new researcher</td>
<td>65%</td>
<td>17%</td>
<td>2%</td>
<td>16%</td>
</tr>
<tr>
<td>Obtaining computer access for new researcher</td>
<td>70%</td>
<td>14%</td>
<td>3%</td>
<td>13%</td>
</tr>
<tr>
<td>Receiving a computer</td>
<td>46%</td>
<td>21%</td>
<td>12%</td>
<td>22%</td>
</tr>
<tr>
<td>Obtaining/installing scientific or statistical software</td>
<td>44%</td>
<td>19%</td>
<td>15%</td>
<td>22%</td>
</tr>
<tr>
<td>Acquiring other IT equipment</td>
<td>28%</td>
<td>25%</td>
<td>19%</td>
<td>28%</td>
</tr>
<tr>
<td>Acquiring non-IT equipment</td>
<td>52%</td>
<td>19%</td>
<td>5%</td>
<td>25%</td>
</tr>
<tr>
<td>Executing a contract for research-related services or products</td>
<td>28%</td>
<td>31%</td>
<td>16%</td>
<td>27%</td>
</tr>
<tr>
<td>Hiring a researcher, from add to start</td>
<td>16%</td>
<td>48%</td>
<td>19%</td>
<td>18%</td>
</tr>
</tbody>
</table>


It also emerged from the interviews that researchers spend significant time on compliance-related activities, so we used the survey to estimate the investment in time on these activities versus other research and patient care-related duties. We found that respondents spent, on average, 10% of their time on compliance (Exhibit 56). This commitment was very high, especially relative to clinical care
duties (18%) and the time spent on applying for grants (14%). These percentages were similar across Services (data not shown).

**Exhibit 56. Time commitments on various activities and duties**

![Graph showing time commitments on various activities and duties]

N=1,034.

A survey of 1,062 VA researchers similar to ours was conducted in 2000. We used similar survey questions, to capture changes in the program and in participant satisfaction that occurred over the past 10 years. Exhibit 57 shows comparisons between the survey in 2000 and our survey implemented in 2011. We found that the research program changed significantly over the past decade. The number of women increased by 9% and the number of researchers who have worked at VA for longer than 10 years increased by 8%. Most strikingly, the percentage of researchers affiliated with BLR&D (or medical service as it was called in 2000) decreased by 42%. The largest growth occurred in HSR&D (21%) and in CSR&D (19%); RR&D increased by 7%.

It emerged from the comparison that many important aspects of the research program had improved since the first survey. We found double-digit increases in satisfaction with the amount of protected time for research (+17%), proposal review process (+15–26%), opportunities for creativity (+30%), ability to use skills (+22%), opportunities for collaboration (+13%), job security (+15%), and overall research environment (+18%). Small to medium improvements occurred in research autonomy (+3%), adequacy of office space (+8%), and local research leadership support (+8%). Finally, the fraction of researchers planning to look for another job decreased by 12%.

However, the levels of satisfaction eroded in some areas. Most notably, researchers were significantly less satisfied with libraries (~25%), computer support (~26%), and laboratory space (~14%). Satisfaction with ORD funding levels, professional training opportunities, access to research assistants and technologists, and mentoring support showed single digit decline.
### Exhibit 57. Comparisons between 2000 and 2001 researcher surveys

<table>
<thead>
<tr>
<th>Comparison variable</th>
<th>% 2000</th>
<th>% 2011</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>24</td>
<td>33</td>
<td>+9</td>
</tr>
<tr>
<td>&gt;10 years at VA</td>
<td>53</td>
<td>62</td>
<td>+9</td>
</tr>
<tr>
<td>BLR&amp;D (medical in 2000 survey)</td>
<td>76</td>
<td>35</td>
<td>-41</td>
</tr>
<tr>
<td>CSR&amp;D (CSP in 2000 survey)</td>
<td>8</td>
<td>27</td>
<td>+19</td>
</tr>
<tr>
<td>RR&amp;D</td>
<td>4</td>
<td>11</td>
<td>+7</td>
</tr>
<tr>
<td>HSR&amp;D</td>
<td>8</td>
<td>28</td>
<td>+20</td>
</tr>
<tr>
<td>Satisfied with amount of protected time</td>
<td>40</td>
<td>57</td>
<td>+17</td>
</tr>
<tr>
<td>Satisfied with proposal review process</td>
<td>43</td>
<td>58--69</td>
<td>+15–26 (^a)</td>
</tr>
<tr>
<td>Satisfied with ORD funding levels</td>
<td>29</td>
<td>21</td>
<td>-8</td>
</tr>
<tr>
<td>Satisfied with autonomy in research</td>
<td>84</td>
<td>87</td>
<td>+3</td>
</tr>
<tr>
<td>Satisfied with opportunity for creativity</td>
<td>56</td>
<td>86</td>
<td>+30</td>
</tr>
<tr>
<td>Satisfied with opportunity to use skills</td>
<td>63</td>
<td>85</td>
<td>+22</td>
</tr>
<tr>
<td>Overall satisfaction with research environment</td>
<td>49</td>
<td>67</td>
<td>+18</td>
</tr>
<tr>
<td>Satisfied with opportunities for collaboration</td>
<td>63</td>
<td>76</td>
<td>+13</td>
</tr>
<tr>
<td>Satisfied with professional training opportunities</td>
<td>51</td>
<td>47</td>
<td>-4</td>
</tr>
<tr>
<td>Satisfied with salary/fringe benefits</td>
<td>49</td>
<td>54/63</td>
<td>+5/+14</td>
</tr>
<tr>
<td>Satisfied with job security</td>
<td>52</td>
<td>67</td>
<td>+15</td>
</tr>
<tr>
<td>Communication within VA services</td>
<td>49</td>
<td>48</td>
<td>-1</td>
</tr>
<tr>
<td>Satisfied with laboratory space</td>
<td>51</td>
<td>37</td>
<td>-14</td>
</tr>
<tr>
<td>Satisfied with office space</td>
<td>49</td>
<td>57</td>
<td>+8</td>
</tr>
<tr>
<td>Satisfied with libraries</td>
<td>59</td>
<td>34</td>
<td>-25</td>
</tr>
<tr>
<td>Satisfied with access to RAs/technologists</td>
<td>43</td>
<td>34</td>
<td>-9</td>
</tr>
<tr>
<td>Satisfied with computer support</td>
<td>46</td>
<td>20</td>
<td>-26</td>
</tr>
<tr>
<td>Satisfied with mentoring support</td>
<td>51</td>
<td>42</td>
<td>-9</td>
</tr>
<tr>
<td>Satisfied with local VA leadership</td>
<td>51</td>
<td>59</td>
<td>+8</td>
</tr>
<tr>
<td>Plans to look for a job</td>
<td>23</td>
<td>11</td>
<td>-12</td>
</tr>
</tbody>
</table>


\(^a\) The 2000 survey measured overall satisfaction with merit review process. We separated the process into fairness (+16%) and funding of best science (+26%).
Research Program as a Tool for Recruitment and Retention at VA

One of the key goals of the research program is to recruit clinicians to VA. Thus, we investigated whether the program is seen as a recruitment tool by the research community and if it played a role in their own decisions to join and stay at VA. The vast majority of survey respondents believed that the program was very important or important to the recruitment and retention of high quality clinicians to VA (Exhibit 58). MDs and MD/PhDs placed more importance on the program than PhDs. In addition, the vast majority of respondents reported that the research program was a factor in their coming to and staying at VA. These numbers were similar for MDs, PhDs, and MD/PHDs (data not shown).

Exhibit 58. The importance of research for recruitment and retention

How important are research opportunities and support to recruiting and retaining high quality clinicians at VA?

<table>
<thead>
<tr>
<th></th>
<th>MD</th>
<th>MD/PhD</th>
<th>PhD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unimportant</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Somewhat important</td>
<td>9</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Important</td>
<td>15</td>
<td>15</td>
<td>26</td>
</tr>
<tr>
<td>Very important</td>
<td>76</td>
<td>73</td>
<td>57</td>
</tr>
</tbody>
</table>

Was the research program a factor in your coming to and staying at VA?

<table>
<thead>
<tr>
<th></th>
<th>Coming</th>
<th>Staying</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>79</td>
<td>90</td>
</tr>
<tr>
<td>MD/PhD</td>
<td>86</td>
<td>94</td>
</tr>
<tr>
<td>PhD</td>
<td>78</td>
<td>92</td>
</tr>
</tbody>
</table>


N=1,034.
However, survey data also showed that the program could be used more effectively as a recruitment and retention tool: 54% of respondents said that they personally knew of an individual who could not be recruited to VA because research opportunities were insufficient (data not shown). Respondents were asked to indicate which of the menu of factors played a role in their acquaintance’s decision not to take a position at VA. The main factor was excessive regulatory burden, reported by 60% of respondents. Insufficient time for research, challenges in obtaining funding and insufficient funding, shortages in support staff, inadequate facilities, and salary all emerged as recruitment challenges (Exhibit 59).

**Exhibit 59. Factors impeding recruitment as reported by the field**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Percent respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive regulatory burden</td>
<td>60</td>
</tr>
<tr>
<td>Insufficient release time for research</td>
<td>36</td>
</tr>
<tr>
<td>Difficulties in obtaining funding for research</td>
<td>35</td>
</tr>
<tr>
<td>Insufficient support staff</td>
<td>34</td>
</tr>
<tr>
<td>Insufficient funding for research</td>
<td>35</td>
</tr>
<tr>
<td>Inadequate facilities</td>
<td>33</td>
</tr>
<tr>
<td>Insufficient salary</td>
<td>34</td>
</tr>
<tr>
<td>Insufficient mentoring</td>
<td>13</td>
</tr>
<tr>
<td>Unknown</td>
<td>4</td>
</tr>
</tbody>
</table>


We also examined how many young researchers decided to remain in academic medicine and at VA. Forty-three percent of respondents said that half or more of their students and postdocs have chosen to pursue careers in academic medicine and 15% said that half or more researchers leaving their group remained at VA (data not shown).

To obtain a VAMC-level perspective, we asked ACOS how often various factors were a challenge to recruitment and retention at their facility. The types of answers that we received were similar to PIs (Exhibit 60), although it appears that higher percentage of ACOS reported these challenges than did members of their communities. The top impediment reported by ACOS was regulatory burden, followed by availability of research/support staff, and funding for research. Adequate salary was reported as an impediment by more than half of the ACOS surveyed.
Exhibit 60. Factors impeding recruitment as reported by ACOS

<table>
<thead>
<tr>
<th>Factor</th>
<th>Percent Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory oversight and compliance burden</td>
<td>83</td>
</tr>
<tr>
<td>Adequate funding support for research</td>
<td>69</td>
</tr>
<tr>
<td>Adequate research and support staff</td>
<td>66</td>
</tr>
<tr>
<td>Amount of release time</td>
<td>66</td>
</tr>
<tr>
<td>Adequate facilities</td>
<td>64</td>
</tr>
<tr>
<td>Adequate research support infrastructure (e.g. IT, library)</td>
<td>60</td>
</tr>
<tr>
<td>Adequate/competitive salary</td>
<td>54</td>
</tr>
<tr>
<td>Adequate equipment</td>
<td>52</td>
</tr>
<tr>
<td>Relationships with academic affiliate</td>
<td>46</td>
</tr>
<tr>
<td>Adequate funds for travel and other discretionary expenses</td>
<td>43</td>
</tr>
<tr>
<td>Availability of professional development programs</td>
<td>27</td>
</tr>
</tbody>
</table>

N=86.
Chapter 6: Results of Research

In this chapter, we examine the quality of VA research and the productivity of the researchers, and how research progress is monitored at the medical centers. Further, we attempted to capture the challenging, but critical question of the impacts of VA research. Finally, we developed and implemented a data collection approach to characterize the innovativeness of the VA environment.

Research Quality and Productivity

The most reliable indicator of high evidence standard in research is its evaluation and endorsement by peers. In the United States (as well as in other developed countries), research projects are validated by peers at least twice in the project life cycle: during the application for funding and during the submission of results to a journal for publication. Promotion through the academic system is largely driven by publications and grants, and therefore the research community is under considerable pressure to apply for funding and to publish their data.

Like all other researchers, the VA community is subject to this scrutiny and these pressures. In addition, most VA researchers have an academic affiliation and have to be successful as scientists to remain at their universities. Therefore, we can infer that VA research meets high standards of evidence if the following are true:

- VA’s intramural peer review process is competitive, rigorous, and results in the identification of best science
- VA researchers obtain funding through competitive review process from non-VA sources
- VA researchers publish their work in respected journals with high impact factors.

Quality check #1: attainment of funding

The peer review process is an evaluation of research by experts knowledgeable about the topic, but not involved in the project. It is used by funding organization to allocate research dollars and by journals to vet articles prior to publication. While peer review has its well-known weaknesses (conflicts of interest, biases against other fields, preference for low-risk projects), it remains the cornerstone of the research enterprise.

Most ORD-funded research projects are peer reviewed. To examine this process at VA we interviewed two extramural reviewers. We were told by these reviewers that the process at VA was very similar to that at NIH (other interviewees shared this view). Reviewers met in person and a typical review panel included 8–10 reviewers evaluating 20 applications, with 3 reviewers per application. Reviewers were drawn from experts both within and outside of VA, with close to equal representation slightly biased toward external experts. The reviewers said that their colleagues generally met the threshold of expertise required to evaluate proposals, but that portfolio managers often struggled to recruit appropriate experts. One of the reviewers mentioned that he had to cover a wide range of topics and was sometimes asked to “stretch into content areas where he did not feel expert.”

233 Interview #51. May 2011.
234 Ibid.
Furthermore, in this reviewer’s experience, the VA panel had few permanent members, which he felt was problematic for consistent review.

According to this reviewer, research portfolio managers were always looking for outside expertise, but it was a particular challenge for VA. That is because VA and NIH are recruiting external reviewers from the same pool of scientists and given that choice, the scientists would review for NIH, because they feel loyalty to the agency that supports their own research and because they see NIH study sections as opportunities to network and to learn about the process. As external reviewers are ineligible to receive funding from VA, these motivations do not apply to them. As a minor issue, the reviewer also mentioned that his tax return containing VA compensation was audited and that this type of experience could be a deterrent to reviewers. He recommended that portfolio managers increase outreach to the extramural community and try to bring in reviewers who have not yet been “captured” by NIH. ORD has entered into a contract with Elsevier for their portfolio management and reviewer management tools which will help to address this issue.

ORD staff acknowledged that recruiting outside reviewers was not easy. For HSR&D, for example, identifying experts outside of VA is difficult because for many types of VA-funded research VA health services researchers dominate this field, and it is difficult to identify outside experts with an appropriate knowledge base (for other types of research, quality of care, for example, there are hundreds of experts in and outside of VA). In addition, even when outside reviewers are identified, program managers are required to obtain approval from the Secretary for non-VA employees to participate in the review session. Furthermore, the review meeting has to be announced in the Federal Register and review panels that include extramural experts must have government employees present at all times. Obtaining IT equipment for reviewers was also mentioned as being difficult. Clearly, these administrative requirements create additional challenges for ORD beyond identifying and recruiting the appropriate experts.

As at NIH, proposals for ORD funding are evaluated based on significance, approach, impact/innovation, investigators and environment. Applications at VA are scored on a scale of 1–5, with 1.0–1.5 = an excellent score and 3.5–5.0 = a poor score (as of 2008, NIH moved from a 1–5 to a 1–9 ranking scale with 1 = exceptional and 9 = poor). We were told by the reviewer that technical merit was the determining factor in proposal evaluation. While relevance to VA mission was also very important, “it never trumped merit.”

Reviewers are not asked to score proposals on mission relevance, and this component of the evaluation is qualitative. The quality of proposals and the feedback provided to the applicants was similar to NIH.

235 Interview #56. May 2011.
236 Ibid.
239 Guidelines for scoring HSR&D proposals. Undated.
241 Interview #51. May 2011.
One of the reviewers we interviewed felt that the process was fair and resulted in the identification of best proposals, although he also noted that the VA process was somewhat less competitive than the NIH process. However, another reviewer with whom we spoke felt that the single study section that he/she attended was ripe with conflicts of interests. According to this person, internal VA reviewers appeared to be unfairly scoring proposals of their rivals. The reviewer felt so negative about the process that he/she does not plan to participate in the review of VA proposals in the future. Given that we heard what appear to be opposing views of the peer review process, we plan to interview additional reviewers to further understand the extent of this problem. ORD is also undertaking an independent review of its grant review process.

The funding success rate at VA – the ratio of submitted to funded proposals – hovers between 20% and 25%. While the process is clearly competitive, it is far less competitive than at NIH, where success rates at some institutes have fallen into single digits.\(^{242}\)

We found that many VA PIs have extramural funding. In FY2010, VA researchers were awarded $515 million by other federal agencies, mostly NIH, and $195 million in non-federal dollars (industry).\(^{243}\) These data suggest that VA researchers are competitive for highly selective NIH funding.

**Quality check #2: dissemination of research findings**

Publications by VA scientists can also be used as an indicator of the endorsement of the work by the scientific community. Most articles are reviewed prior to publication by at least three experts in the field, who evaluate the quality of evidence and soundness of conclusions. The standards for publication can be very high, especially for top-tier journals, such as *Science* and *Nature*, which can publish only a small number of articles submitted by the research community. Furthermore, most journals require that the authors describe the methodology used in the paper in sufficient detail for it to be reproducible, and so researchers are aware that their conclusions must be supported by reliable data and can be potentially double-checked by another group.

To determine how many papers VA researchers publish per year, we performed two analyses. First, we searched the database called “Web of Science” for all publications that included a VA address. This search included all researchers who have any type of affiliation with VA. Exhibit 61A shows that VA researchers publish thousands of papers per year, and that the number of publications has steadily increased over the period examined. In addition, we examined publication records of the ORD-funded PIs, who are the core of the VA research community. We found that 1,926 researchers published 2,753 papers in 2010, or 1.5 publications per researcher (Exhibit 62B). Boyack et al. found that NIH-funded investigators publish 1.7 papers, on average.\(^{244}\) Note that Boyack used several publication databases to arrive at his estimate and had more complete publication coverage, which is likely to result in a higher average. Thus, VA researcher productivity is comparable to or slightly below that of the investigators supported by NIH. The papers published by the VA-funded investigators surveyed were cited, on average, by 3.4 other papers and had an average journal impact factor of 5.1. Note that only 6% of science journals have an impact factor higher than 5.\(^{245}\)

\(^{242}\) Ibid.

\(^{243}\) Data obtained from ORD.


\(^{245}\) Calculations by Abt Associates for Journal Citation Report 2010 list of impact factors.
Exhibit 61. Publication outputs of VA researchers

A. Number of publications with VA-affiliated authors. 2004–2010.

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>8,732</td>
</tr>
<tr>
<td>2005</td>
<td>8,910</td>
</tr>
<tr>
<td>2006</td>
<td>9,050</td>
</tr>
<tr>
<td>2007</td>
<td>9,167</td>
</tr>
<tr>
<td>2008</td>
<td>9,223</td>
</tr>
<tr>
<td>2009</td>
<td>9,729</td>
</tr>
<tr>
<td>2010</td>
<td>10,142</td>
</tr>
</tbody>
</table>

B. Number of publications with ORD-funded PIs as authors. 2010.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PIs used in the search</td>
<td>1,890</td>
</tr>
<tr>
<td>Number of publications</td>
<td>2,753</td>
</tr>
<tr>
<td>Number of publication per PI</td>
<td>1.5</td>
</tr>
<tr>
<td>Average citations</td>
<td>3.4</td>
</tr>
<tr>
<td>Average IF</td>
<td>5.1</td>
</tr>
</tbody>
</table>

Source: Web of Science.

A. The following key words were entered into the address field: “va healthcare or va health care or va palo alto hth care syst or san diego vet affairs healthcare syst or va puget sound or va greater los angeles or va san diego or va pittsburgh or va boston or va maryland or va hospital.” This search strategy was suggested by ORD. Search conducted on August 22, 2011.

B. The list of names obtained from ORD for all currently or recently merit funded PIs/CSP investigators, and Coe/REAP directors in 2010 was used as a query in Web of Science. The search was performed as follows: AU=(author last name first name OR author last name first name…) AND AD=(Veterans administration OR VA medical center OR Veterans affairs OR VAMC OR VA healthcare). Search conducted on October 5, 2011.

The VA research community appears to be particularly influential in the area of comparative effectiveness research (CER). An examination of two top medical journals, The New England Journal of Medicine (NEJM) and The Journal of the American Medical Association (JAMA) by ORD leadership revealed that 25% of CER studies published in these journals had a VA author.246

Quality check #3: facility-level monitoring

Like many academic departments, VAMCs monitor PI performance. To examine how performance is measured in the field, we asked all ACOS to report in the survey who is responsible for monitoring research productivity and what indicators are used. We found that in 82% of cases research performance monitoring is the responsibility of an ACOS, followed by an R&D committee (Exhibit 62). Note that these categories are not mutually exclusive, as respondents were asked to select all of the options that apply to their facility. In fact, we received 192 total answers, suggesting that respondents selected two options on average (data not shown).

Exhibit 62. Who monitors productivity at the VA medical centers

We found that in most responding facilities, productivity is measured by the number of publications and leveraged research dollars (Exhibit 63). Quality of publications and number of awards and presentations were also used, by approximately a third of the facilities. Some facilities use knowledge transfer indicators – the number of inventions and devices – to evaluate the productivity of their community. Each ACOS selected four options, on average, based on the total number of answers.

Note that affiliate university departments also collect performance data from VA researchers with academic appointments. These data are used in promotion and tenure decisions. However, universities frequently fail to track VA funding or consider it to be as meritorious as NIH funding. According to a Center of Excellence director at a top tier research university, all VA researchers in his Center have an academic affiliation and are subject to the same performance evaluation as full-time university faculty.247 In our survey of researcher, we found that 95% of respondents had an academic affiliation.

N=84.

Exhibit 63. Indicators of productivity used at VAMCs

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Percent respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of publications</td>
<td>80</td>
</tr>
<tr>
<td>Research dollars generated by VA investigators</td>
<td>79</td>
</tr>
<tr>
<td>Extramural research dollars generated by VA investigators</td>
<td>73</td>
</tr>
<tr>
<td>Quality of publications</td>
<td>39</td>
</tr>
<tr>
<td>Number of presentations</td>
<td>33</td>
</tr>
<tr>
<td>Number of awards/honors</td>
<td>32</td>
</tr>
<tr>
<td>Number of invention disclosures, patents, and licenses filed</td>
<td>20</td>
</tr>
<tr>
<td>Number of devices</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
</tr>
<tr>
<td>My facility does not measure productivity</td>
<td>5</td>
</tr>
</tbody>
</table>


Impacts of VA Research

Measuring the impacts of research on a patient continues to be a challenge to the scientific, funding, and policy communities. Research performance is generally assessed using outputs, such as publications, leveraged funding, students trained, and patents filed. These measures are quantitative, clearly defined, and relatively easy to obtain, explaining their widespread use in the evaluation of scientific success and promotion decisions.

Because of the increasing demands for accountability, federal agencies and the research community began to develop additional approaches to measuring the outcomes of investments in research. One approach is traditional economic analysis, which estimates the benefits of research in dollar terms by linking research expenditures to reduced mortality and morbidity resulting from advances in biomedical research. Another approach is to seek input from the investigators conducting research on the expected or demonstrated benefits of their projects. This method was used by Stryer and colleagues at the Agency for Healthcare Research and Quality (AHRQ) to assess the outcomes of research supported by AHRQ. In the Stryer study, researchers were asked to provide their “most salient findings and to


supply material for up to three slides.” Eleven categories were then used to group these reported findings.

Based on these data, AHRQ staff developed a framework of outcomes that included four levels of impacts from most to least significant: on health care outcomes, on clinical outcomes, on policies, and on research. Kuruvilla and colleagues proposed a more general research impacts framework. This framework included four areas of impact: research-related impacts; policy impacts; service impacts; and societal impacts. Within each of these areas the authors identified several descriptive categories.

We adapted the approaches of Stryer and Kuruvilla to assess the impacts of the VA research program. Like Stryer, we used a survey of researchers to collect self-reported data on impacts. The impact measures that we used were more similar to those suggested by Kuruvilla. Because the Stryer framework was developed for health services research, we felt that it was too limited for the much broader VA research portfolio. Our measures of impact were developed in collaboration with ORD leadership, whose knowledge of the program was instrumental in ensuring that the impact indicators were relevant and inclusive of the broad range of research areas.

These indicators were included in the survey of VA researchers. Individuals who self-identified as basic researchers or clinical/rehabilitation/health services researchers were presented with two different sets of impact options and asked to indicate with a “yes” or “no” whether their projects produced these impacts (Exhibit 64). Respondents indicating key impacts (for example, changes in the way health care is delivered in clinical practice) were asked to elaborate about the impact in the space provided.

As we had limited time for the analysis of survey data, in this draft we report only quantitative measures of impact. The data showed that the VA research community has made great contributions at all impact levels – from basic science (96% of BLR&D researchers) to reduction in health care costs (33% of non-BLR&D researchers), and even to improvements in life expectancy and quality of life (16% and 60% of non-BLR&D researchers, respectively). While these impacts were self-reported, they were a mix of subjective and objective measures. For example, an improved understanding of disease mechanism, reported by 96% of basic and 47% of all other researchers, is subjective. In contrast, follow-up funding from other sources, reported by 84% of basic researchers, is a verifiable fact. Citations counts on PIs’ papers will be used to validate comments about the impact on the research community. In addition, for several key indicators we requested survey respondents to provide brief elaboration. These data will be used to validate the answers as well as to classify “other” benefits to the Veterans reported by over 60% of all researchers.

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252 PIs were asked in the survey to list three of their most significant publications.
### Exhibit 64. Impacts of VA research

<table>
<thead>
<tr>
<th>Did your research result in ...</th>
<th>Yes, N (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For basic researchers (N=350)</strong></td>
<td></td>
</tr>
<tr>
<td>Improved understanding of the disease mechanism (^{(a)})</td>
<td>443 (96%)</td>
</tr>
<tr>
<td>Follow-up funding from VA or from other sources (^{(a)})</td>
<td>292 (84%)</td>
</tr>
<tr>
<td>Identification of unknown side effects of a clinical intervention</td>
<td>40 (12%)</td>
</tr>
<tr>
<td>Significant impact on your field (^{(a)})</td>
<td>328 (94%)</td>
</tr>
<tr>
<td>Significant impact on another field</td>
<td>191 (55%)</td>
</tr>
<tr>
<td>Other benefits to Veterans (^{(a)})</td>
<td>216 (62%)</td>
</tr>
<tr>
<td><strong>For clinical, rehabilitation, and health services researchers (N=650)</strong></td>
<td></td>
</tr>
<tr>
<td>Improved understanding of the disease mechanism</td>
<td>306 (47%)</td>
</tr>
<tr>
<td>Submission for FDA approval or a decision to not submit for FDA approval</td>
<td>68 (11%)</td>
</tr>
<tr>
<td>Clinical trial</td>
<td>344 (53%)</td>
</tr>
<tr>
<td>The use of a new drug, drug regimen, or other novel treatment (^{(a)})</td>
<td>200 (31%)</td>
</tr>
<tr>
<td>New testing or screening approaches (^{(a)})</td>
<td>233 (36%)</td>
</tr>
<tr>
<td>Better patient education</td>
<td>308 (48%)</td>
</tr>
<tr>
<td>Better provider education</td>
<td>355 (55%)</td>
</tr>
<tr>
<td>Identification of unknown side effects of a clinical intervention</td>
<td>84 (13%)</td>
</tr>
<tr>
<td>Changes in the way health care is delivered in clinical practice (^{(a)})</td>
<td>301 (47%)</td>
</tr>
<tr>
<td>New or expanded disease management approaches (^{(a)})</td>
<td>311 (48%)</td>
</tr>
<tr>
<td>Improvements in patient life expectancy</td>
<td>101 (16%)</td>
</tr>
<tr>
<td>Improvements in patient quality of life</td>
<td>388 (60%)</td>
</tr>
<tr>
<td>Development of new devices to help disabled Veterans (^{(a)})</td>
<td>52 (8%)</td>
</tr>
<tr>
<td>Reduction in health care costs</td>
<td>211 (33%)</td>
</tr>
<tr>
<td>Other benefits to Veterans (^{(a)})</td>
<td>413 (64%)</td>
</tr>
</tbody>
</table>

*Individuals who chose “yes” for these options were asked for an elaboration.*

*Source:* Abt Associates.

\(N_{\text{basic}}=350; \; N_{\text{clinical}}=268; \; N_{\text{rehab}}=107; \; N_{\text{helthserv}}=277.*
To obtain additional data on the potential impact of VA research on Veterans, we asked the research community to indicate whether they agreed or disagreed with several statements describing the program. As Exhibit 65 shows, the vast majority said that the program has made a difference in how care is delivered to Veterans and made contributions to important areas of research (83% and 82%, respectively). Three-quarters believed that that the program is a clinician recruitment tool and 57% that it has already reduced or will reduce health care costs. Almost half of the researchers agreed that funding for many topics supported by ORD may be limited or unavailable outside of VA.

**Exhibit 65. Respondent views on the benefits of research program to Veterans**

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Percent agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Because of program focus on Veteran conditions, funding for many research projects may be limited or unavailable from other funding agencies</td>
<td>46</td>
</tr>
<tr>
<td>Research conducted by the program has reduced or will reduce health care costs</td>
<td>57</td>
</tr>
<tr>
<td>VA research is uniquely positioned to relatively quickly implement research findings in clinical practice</td>
<td>59</td>
</tr>
<tr>
<td>Research program is a tool to recruit talented clinicians into the VA system</td>
<td>75</td>
</tr>
<tr>
<td>VA researchers are breaking new ground in the areas of fundamental importance within and outside of VA, e.g. mental health and substance abuse</td>
<td>82</td>
</tr>
<tr>
<td>The program has made a difference in how care is delivered to Veterans</td>
<td>83</td>
</tr>
<tr>
<td>VA research community is committed to improving the lives of Veterans</td>
<td>92</td>
</tr>
<tr>
<td>None of the above is true</td>
<td>1</td>
</tr>
</tbody>
</table>


**Innovation at VA**

What is innovation? The Merriam-Webster dictionary offers two definitions of innovation: a new idea, method, or device; and the introduction of something new. This definition highlights the dual nature of innovation – a creative process of concept development as its initial stage, followed by translation of an innovative idea into a practical application that would impact the target population and society at large.

**An approach to measuring innovation**

Most of the studies on innovation focus on the characteristics of organizational environments that might facilitate or inhibit innovation. Because of its somewhat abstract nature, innovation itself is more

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difficult to quantify, especially as applied to research, and we were unable to identify any sources that “operationalized” and measured this construct. Innovation and creativity scholars use research outputs, such as patents and publications, as proxy measures for innovation.

We settled on the following approach to this Research Issue. First, we identified from the literature various characteristics of organizational environments that have been linked to innovation and adapted these characteristics to the VA research program. Second, we examined whether and to what extent innovation facilitators are present in the VA environment, using the survey of researchers. Third, we examined the organization and funding structure of DARPA, a mission-driven federal entity with a reputation for innovativeness, to determine whether any of the processes at this organization can be adopted by VA. Our findings are described in the rest of this chapter.

The complexity of current scientific problems requires solutions that combine the knowledge, efforts, and abilities of many researchers with diverse backgrounds and levels of expertise. A typical biomedical research group, for example, would consist of a Principal Investigator; postdoctoral, doctoral, and undergraduate students; and laboratory technicians.255 This complex scientific environment and the collaborative nature of the modern research enterprise has motivated innovation and creativity researchers to shift their attention from individuals to their environments.

For example, in a study of 30 university and industry-based groups in biotechnology in Sweden, Hemlin attempted to identify features of laboratory environments that distinguished creatively “excellent” from “less excellent” groups.256 Creative excellence appeared to be primarily related to three factors: social—atmosphere of support and encouragement within the group, composition and size of the group, and good group communication; cognitive – organizational and individual knowledge, research autonomy, and high standards and quality; and leadership.

Hollingsworth analyzed research environments in several leading institutions in the United States and Western Europe and identified four organizational characteristics that could adversely affect the discovery process.257 These included differentiation (a type of organization with sharp boundaries between research units); hierarchical authority (centralized decision-making); bureaucratic authority (high level of rule standardization); and hyperdiversity (excessive diversity in types of expertise that was deleterious to communication).

Gretchen Jordan of Sandia Laboratories identified 42 positive attributes of innovation, grouped into four domains: exploration, autonomy, and integration; organizational strategy and investment; resources,


255 Some innovative organizations (for example, think tanks) are not affiliated with universities and have few students.


control, and support systems; and people, rewards, and management.\textsuperscript{258} Teresa Amabile and colleagues developed a similar framework for assessing creativity potential: positive factors in her framework included encouragement of creativity, autonomy and freedom, and adequate resources; negative factors included organizational impediments and workload pressures.\textsuperscript{259} This conceptual model was used to develop a 78-item paper and pencil survey, with each item describing a characteristic of the work environment that was then scored on a numerical scale.

Another more recent study by Lee and colleagues reviewed articles by Harvard University basic science investigators in several of its medical campuses between 1993 and 2003.\textsuperscript{260} Citation counts for articles decreased as distances between the authors (including between first and last) increased. The authors concluded that proximity of investigators is an indicator of an impact of the collaboration.

As consensus characteristics important for innovation began to emerge, we considered how to apply this approach to the VA research program. VA is a unique research organization in at least two ways. First, unlike academic institutions it is mission-driven and is subject to shifting priorities and political pressures. In addition, unlike any other program in the United States, the VA research program is embedded in the health care system. Therefore, some of the measures of innovation proposed in the studies mentioned above were not applicable to VA, while other factors important to VA were not collected. For instance, as many VA researchers have clinical duties, protected time for research is an extremely important factor for the VA research community, but might be irrelevant at other organizations. Based on our understanding of the VA program, we adapted innovation frameworks developed by other scholars as shown in Exhibit 66. The framework includes five facilitators of innovation:

- Organizational strategy and investment
- Autonomy and freedom to conduct research
- Research resources
- Support systems
- Rewards and professional development.

For each of these domains, we developed a set of performance indicators, which we then measured in the survey of researchers.


Exhibit 66. Framework for measuring facilitators of innovation at VA

<table>
<thead>
<tr>
<th>Innovation domains</th>
<th>Performance indicators</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| Organizational strategy and investment  | • Fairness of funding allocation  
• Balanced portfolio  
• Satisfaction with quality of research  
• Perceived commitment to mission  
• Perceived work impact                                                               |         |
| Autonomy and freedom                    | • Autonomy to choose research direction  
• Opportunity to think creatively  
• Sense of control over work and ideas                                               |         |
| Research resources                      | • Equipment  
• Facilities  
• Office space  
• Laboratory space  
• Libraries and other reference sources  
• Amount of funding support  
• IT support  
• HR support  
• Access to reagents, equipment, and data  
• Release time  
• Access to students                                                                    |         |
| Support systems                         | • ACOS support  
• Clinical supervisor support  
• Professional training opportunities  
• Mentoring                                                                            |         |
| Rewards structure and career advancement| • Salaries and benefits  
• Benefits  
• Recognition  
• Promotion  
• Opportunities for career advancement  
• Job security  
• Appropriateness of success measures                                                   |         |

Source: Abt Associates.

Measuring innovation at VA

In the survey of VA-funded researchers, we asked respondents to indicate on a scale of 1–5 to what extent they were satisfied with various aspects of their research environment, such as access to students, adequacy of funding support, freedom to think creatively, and others. Our scale was as follows: 1=strongly dissatisfied; 2=dissatisfied; 3=neutral; 4=satisfied; and 5=strongly satisfied. The average score was then calculated for each indicator by multiplying the number of respondents choosing a particular answer option by the score and then dividing the resulting total by the number of individuals responding to the question. These average values provide an indicator of the adequacy of the process being measured, with the score of 5 being the highest possible value.  

261 For most questions, percent of missing data was <1%.
Exhibit 8 shows the results of the survey, with each bar representing an individual question. We found that research resources were the least favorable aspects of the environment: the indicators for IT support, HR support, and facilities were ranked at below 3, which was worse than neutral (Exhibit 67). The highest ranked aspects of the research environment were associated with autonomy and freedom to conduct research. Respondents ranked opportunity to think creatively and autonomy in choosing research direction at 4.22 and 4.26, respectively, and control over work and ideas at 3.92. All indicators of organizational strategy, support systems, and reward structures received rankings of 3 or higher, which means that the group was neutral to positive about these aspects of the environment. Support structures in particular – support from ACOS and the clinical supervisor, mentoring, and professional training opportunities – received high scores.

Exhibit 67. Characteristics of VA research environment


N=1,034.
In the survey, we also asked respondents to indicate whether they have received any grant or award for innovative research since joining VA. Almost 40% (328 out of 884) responded in the affirmative (data not shown).

**An innovative federal organization: Defense Advanced Research Project Agency**

The Defense Advanced Research Projects Agency (DARPA) deserves special mention here because of this organization’s mandate of “radical innovation for national security.” Several key features distinguish DARPA from other federal entities that support research. First, a specific problem is defined by the agency’s staff; moreover, DARPA portfolio managers seek input from military and intelligence staff (i.e., the end users) before the problem is advertised to the applicants. Once the problem is defined, DARPA solicits proposals for specific solutions from the research community. This approach is very different from how ORD funds research. While ORD leadership and other stakeholders have some influence on the research community, the research is primarily driven by the interests of VA investigators. In addition, DARPA can solicit proposals from the entire extramural community. VA research program is intramural.

Second, DARPA solicitations often call for teams rather than individuals to solve a problem. VA does take advantage of this approach by supporting research Centers of Excellence, REAPS, and QUERIs, which are intended as collaborative efforts. Third, DARPA has very specific and strict investment criteria. As described by a former director of the DARPA Defense Science Office, program managers must answer the following questions for each project in their portfolio:

- What is the project trying to accomplish?
- What is the current approach and what are its limitations? How will these limitations be removed to improve performance? How much will performance be improved (e.g. by a factor of 10, 100)?
- If successful, what difference will it make to whom?
- What resources are required? What is the time frame? How much will it cost?
- What is DARPA’s “exit strategy”? Who will adopt the technology and turn it into new capability or new product?

In contrast, proposal evaluation criteria used at VA, are heavily weighted toward proposal technical merit, feasibility of the approach, and the record of the investigator, rather than the particular capability resulting from the research project. Furthermore, a grant from VA or other federal sponsors represents a financial commitment, and will not be revoked short of unethical conduct of research, funding shortages, or other extreme circumstances. In contrast, DARPA reserves the right to terminate a project at any time, if it no longer meets the needs of the organization.

DARPA is an agile and lean organization, with approximately 120 technical staff and only one level of supervision between program managers and the agency director. Projects, program managers, and

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even the director rarely stay at the agency for longer than five years and grant renewals are rare. This constant turnover of personnel and projects brings in energy and new ideas. Program managers are continuously engaged in discussions with university researchers and industry about new technological opportunities. Importantly, program managers are empowered to make decisions about the direction of the project, its funding, and its duration. Finally, DARPA has an unprecedented flexibility and speed in hiring staff, issuing contracts, and paying competitive wages. VA, in contrast, is a highly regulated and closely monitored organization that is subject to pressures from various stakeholders with diverse interests. Its hiring and contracting processes are slow and rigid, and it uses standard government pay scales. Its management and leadership structure is extensive and complicated, which results in slow decision-making processes.

In conclusion, if ORD is interested in increasing the innovativeness of its research program, it can apply some of the best practices developed by DARPA. For example, ORD could adopt additional proposal evaluation criteria similar to DARPA’s for projects or programs focused on the development of new technologies or capabilities. In addition, ORD should continue to support collaborative, interdisciplinary projects through various center funding mechanisms, as these types of team projects are associated with innovation. Finally, more flexible and efficient hiring, purchasing, and contracting are important for conducting cutting-edge research, although we realize that ORD may have limited authority to improve these support processes.

This section concludes the presentation of our findings on the research program structure and composition, adequacy of resources and support systems available to the researchers, and the quality/impacts of VA research. After reviewing this report, VA selected two problems, which were subjected to more in-depth analysis in an attempt to identify solutions. The results of that study are described in the next chapter.
Chapter 7: Resolution of Two Problems Selected by VA

Large-scale and systematic data collection efforts in the first phase of the project revealed several problems faced by the research community. The problems fell into the following categories:

1. Inadequate OI&T support for research programs, including lack of customer orientation, inadequate access to equipment and tools, and inflexible data access policies
2. Inefficient hiring and access to facilities policies, including excessive clearance requirements and delays in hiring
3. Undue regulatory burden, including excessive training requirements and frequent compliance-related visits
4. Inadequate funding support, including amount and duration of awards, lack of travel funds, and funds to support regulatory oversight
5. Ineffective communication, including communication of research advances to Veterans, the use of the Communications Office for dissemination of findings, and communication between the field and the Central Office.

After reviewing the interim report describing our findings, the Office of Policy and Planning (OPP) and the Office of Research and Development (ORD) identified two problems for further study in the second phase of the project. Problem 1 (selected by ORD) comprised a set of issues related to regulatory burden, which emerged very strongly as a concern in ACOS interviews and in the survey of ORD-funded investigators. Problem 2 (selected by OPP) focused on funding strategies for the research program. While we have not examined this aspect of the research program in great detail in Phase I, this issue is of great importance both to OPP and to ORD, in particular given the possibility of future budget cuts. The rationale for selection of these two problems, as well as the general approach to their analysis, was presented to the OPP and the ORD leadership in August, 2011 and was positively received. In this chapter, we describe our in-depth analysis of the two problems and recommend several solutions.

Problem 1 – Excessive Regulatory Burden

How can VA reduce and refine the regulatory burden in order to enhance research innovation and productivity?

Based on the data collected in the interviews and PI survey, we identified three regulatory areas perceived as a burden by the research community:

1. Excessive rules and regulations related to human subjects protection, which do not offer additional benefits to Veterans
2. Overly restrictive policies for accessing, sharing, and disseminating VA data, which are disproportionate to the sensitivity of the data
3. Excessive training requirements, unnecessarily frequent training, and duplicative training for researchers with joint VA/university appointments.
We hypothesized that given the size of the research community at VA, real cost savings and increased productivity might be achieved by eliminating excessive requirements. We approached Problem 1 by examining the origins of each element of burden and the costs of compliance to VA.

**Problem Area 1a: Excessive rules and regulations related to human subjects protection**

According to several Associate Chiefs of Staff (ACOS) interviewed, VA policies and procedures for protecting human subjects participating in research are excessively burdensome, without offering additional safeguards to Veterans. ACOS believed that high regulatory burden is the result of the disproportionate response by VA to a small number of isolated incidents which occurred at a few medical centers. While well-intended, some of these policies are perceived by the research community as not only unnecessary, but potentially weakening the very protections these policies are designed to reinforce. One example often mentioned was the increasing length and complexity of consent forms due to the many required elements that the forms must contain. ACOS thought that study subjects were less likely to read and/or understand longer and more complicated forms. We were also told by several respondents that excessive regulatory requirements have created an atmosphere at VA where staff seek loopholes and “workarounds” that would help them minimize delays in their research. Finally, researchers expressed resentment that the organization did not trust them to use their knowledge, judgment, and professional ethics to protect Veterans.

The guidelines for protecting human subjects participating in research are described in VHA Handbook 1200.05. To find solutions to reduce burden, we initially planned to review this Handbook to identify those rules and regulations that are not required by law and which offer little or no additional protections to Veterans participating in research beyond those regulations that are legally required. As we began this task, however, we learned that ORD staff had already combed through the Handbook and determined which requirements exceeded the Common Rule and which were the same or similar. Using this information, we focused on the requirements that exceeded the Common Rule, as we saw these as potential targets for elimination.

**Burden and its sources.** The Handbook 1200.05 requirements exceeding the Common Rule were of three types:

- Requirements that resulted in additional administrative tasks
- Requirements that resulted in additional layers of oversight
- Requirements that resulted in longer consent forms.

Most requirements exceeding the Common Rule were administrative in nature. While each additional requirement seemed minor, together they could add up to considerable costs in time and resources. For example, section 16.103(b)(2) of the Common Rule simply states that one or more IRBs must be established to review research protocols and that adequate space and support staff should be made available to hold IRB meetings. VA Handbook 1200.05 (paragraph 5g1) expands this guidance by incorporating specific requirements related to meeting space: the IRB meeting room must be private and secure record storage must be available at the meeting site. These additional specifications will necessitate locating and booking rooms with secure storage for each IRB session, which might be unnecessary if IRB members were to bring all the materials with them. In another expansion of the Common Rule, minutes from the IRB meetings must be provided to the R&D Committee (1200.05 Paragraph 26 h3). Assuming that IRBs already keep detailed records of all the proceedings (which is required by other rules), the value of creating and filing additional copies for the R&D Committee is unclear.
The status of IRB members unaffiliated with VA is another example of a simple requirement being expanded in seemingly unproductive direction. The Common Rule states that at least one member unaffiliated with the institution must be included in an IRB (section 16.107(d)). Handbook 1200.05 (paragraph 12g) further specifies that an unaffiliated member with voting privileges must obtain a “Without Compensation” (WoC) appointment. During the first phase of the study we found that the process for obtaining WoC appointments often takes several months. Thus, the modification introduced by VA is likely to add substantial delays to the timing of IRB review and require VA staff time to process WoC paperwork, without any obvious benefit. Furthermore, the need to go through the WoC appointment process may discourage unaffiliated experts from serving on VA IRBs, potentially creating recruitment challenges and reducing the quality of the Boards. We understand that some VAMCs, for example Boston Medical Center, have been able to work out an arrangement that allows bringing in IRB members without a WoC appointment.\textsuperscript{264} We do not know, however, whether other facilities have been able to avoid going through this step.

The informed consent process also requires seemingly unnecessary administrative tasks. The Common Rule (16.117a) mandates that a written informed consent is signed by the subject or his/her legally authorized representative and that the individual signing the form retains a copy. VA consent procedures are more extensive. First, the consent form must be signed and dated by both the subject and the person obtaining it. In addition, the original signed and dated form must be filed by the investigator and be readily accessible for auditing. Yet further, if the subject submits the signed consent form by fax, the receiver of the form must also sign and date it. Finally, for studies involving an invasive procedure or an investigational drug/device, consent forms must also be signed by witnesses, although we were told that this requirement will be lifted. Thus, in some cases, the VA standard operating procedures require that consent form is signed by (1) the subject or designee; (2) witness; (3) the PI on the study; and (4) the administrative assistant receiving the fax.

VA requirements for what information must be contained in consent forms also exceed the Common Rule. Extraneous items include one or more of the following: (1) disclaimer about whether the specimens obtained in the study will result in commercial product; (2) future use of specimens; (3) future use of data; (4) re-contact information; (5) payment for participation; and (6) disclosure of results (Handbook 1200.05 Paragraph 32b). We were told in the interviews that the length of consent forms has increased significantly over the past few years. For example, a consent form for simple cases involving drawing blood from healthy volunteers has grown from one page to four. For studies that involve real risk to participants, the form can be as long as 20 pages. The average length of consent forms is 5–6 pages.\textsuperscript{265} Developing longer consent forms increases burden on the PIs running the study and on the IRBs reviewing the protocol, while potentially compromising research subjects’ understanding of the risks. While some or all of this additional information might be relevant in some cases, it might be more efficient to have these items be optional and left to the discretion of the PI running the study, rather than be mandated for each consent form.

In Phase I of the project we learned that many researchers were unsatisfied with the length of time to obtain IRB approvals. It took 53% of survey respondents 1–3 months and 21% 4–6 months to get approvals; 46% of respondents disagreed or strongly disagreed with the statement “time required for IRB approval is appropriate.” Some of these delays are likely to result from additional layers of approvals introduced by VA which exceed the Common Rule. For example, the VHA Handbook

\textsuperscript{264} Physician/scientist at Harvard Medical School. Personal communication.

\textsuperscript{265} Interview #12. February 2, 2011.
mandates that the institutional Privacy Officer (PO) and Information Security Officer (ISO) must approve an exempt study before initiation (1200.05, paragraph 25e). This additional level of approval is likely to delay research. Furthermore, some ACOS told us that POs and ISOs at their facilities were unqualified to make IRB-related decisions; at least one facility reported an adversarial relationship with its Privacy Officer, who was holding up studies. VA also requires that all research protocols, including exempt research, be approved by the R&D Committee before any work can begin (1200.5 paragraphs 9 and 15). If the R&D Committee meets once a month, this requirement alone can delay research by several weeks. Finally, research involving pregnant women, children, and prisoners as well as research performed outside of the United States requires a waiver from the Chief Research and Development Officer (1200.5 paragraphs 46–48). Obtaining these waivers also delays initiation of research. We believe that it would be worthwhile for ORD to examine whether it makes more sense to shift all decisions related to human subjects research to IRBs rather than requiring researchers to undergo additional levels of review.

Finally, VA requirements placed on affiliated institutions (teaching hospitals and medical centers) appeared excessive. Handbook 1200.05 states that the affiliate institution IRB “must report its findings and actions to the investigator, the ACOS/R&D, and the R&D Committee” (1200.05 paragraph 14a). Further, affiliate institution IRBs are required to include two members from VA, who are empowered to make decisions on non-VA research matters, if relevant (1200.05 paragraph 7c). It is not specified in the Handbook what these matters might be. In our view, such wide-reaching rules might discourage universities from collaborating with VA.

**Problem Area 1b: Overly restrictive policies of accessing, sharing, and disseminating VA data**

In the survey of VA researchers, IT support for research emerged as a serious weakness of the VA research infrastructure. We found that the research community was dissatisfied with virtually all aspects of IT support. For example,

- 72% of respondents disagreed or strongly disagreed with the statement “it is easy to link equipment to the VA network”
- 59% reported that it was difficult to take VA data to be presented outside of VA
- 43% thought that data protection policies were not appropriate to the level of data sensitivity
- 42% said that VA policies for data access did not meet their needs.

Moreover, the level of satisfaction with IT services has fallen by 26 percentage points since it was last systematically examined in the survey of researchers conducted in 2000. This decline was larger than in any other area for which comparison data were available.

We chose to focus on two IT-related issues important to research: definition of sensitive data and handling of research data. In order to identify potential solutions to the problems communicated via the survey, we examined whether VA policies are comparable, less restrictive, or more restrictive than those at NIH intramural programs, which we believe is an appropriate comparison.

**Burden and its sources.** We found that definitions of Personally Identifiable Information (PII), or Personal Sensitive Information (PSI) as it is called at VA, were virtually identical (Exhibit 68).
Exhibit 68. Definitions of PII at VA and NIH

<table>
<thead>
<tr>
<th>VA</th>
<th>NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any information about an individual maintained by an agency, including any information which can be used to distinguish or trace individual’s identity, such as their name, social security number, date and place of birth, mother’s maiden name, biometric records, or any information that is linked or linkable to an individual. Education, financial transactions, medical history, and criminal or employment history are included.(^{266})</td>
<td>Any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual’s identity, such as name, Social Security number, date and place of birth, mother’s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.(^{267})</td>
</tr>
</tbody>
</table>

However, in contrast to VA, at NIH this definition is followed by a list of examples of non-sensitive information, including:\(^{268}\)

- Primary research data that does not support an employee intervention report or patent application and/or does not contain moderate or high PII
- Manuscripts (submitted or in preparation) that are intended for publication in a public archive such as a journal or book
- Presentation materials intended for public disclosure
- Other information that is publicly available or has been made public
- Post award grant and contract data
- De-identified patient research data
- Data encrypted using FIPS 140-2 technologies.\(^{269}\)

Note that these are the same data types that are seen by the research community as excessively and unnecessarily regulated at VA.

We shared some of the problems identified by the researchers with the Office of Information and Technology (OI&T). In response, OI&T staff sent us a PowerPoint presentation, which included a slide describing the sensitivity of research data.\(^{270}\) This slide stated that:

- Non-human research data are almost always NOT sensitive (some rare exceptions)
- Primary human subjects data (individual subjects) are usually sensitive, with varying degrees of risk


\(^{268}\) Guide for Handling Sensitive Data at the NIH. Quoted verbatim


\(^{270}\) Office of Research and Development – OI&T partnership. Presentation by James L. Breeling, MD and Darryl McGraw, CIO for ORD. Not dated.
• Aggregate data are NOT\(^{271}\) sensitive
• Manuscripts and grants/protocols are not considered sensitive from the organization’s perspective.

As OI&T staff clearly makes a distinction between various types of research data, we are uncertain why the community continues to report that animal and aggregate data are treated in the same way as PII. It is possible that the IT personnel in the field do not know of these exemptions, as they are not included in the Handbook 6500 or other IT-related policy documents which were shared with us. Alternatively, the local IT personnel know that not all research data are sensitive, but prefer not to take responsibility for making the sensitivity determination.

Many other problems with IT support reported in the survey flow from indiscriminately treating research data as sensitive. For example, VA rules dictate that sensitive information may not reside on non-VA owned equipment, unless approved by the VA’s Chief Information Officer. If approved, the non-VA systems and devices must conform to, or exceed, VA security policies.\(^{272}\) While this policy might be reasonable for truly sensitive information, it becomes a serious impediment to research if applied too broadly. For example, 95% of VA researchers who responded to our survey have university appointments and potentially use both VA and affiliate computers. If all research data are viewed as sensitive, these individuals would be unable to move de-identified or animal data between their own computers or share these data with university colleagues.

VA is aware of IT-related challenges faced by the research community. In 2010 VA, the Association of American Medical Colleges, and NIH convened a Working Group to develop policies that would facilitate data sharing between VA and affiliate institutions.\(^{273}\) The Working Group published a report recommending that VA “modify policies and procedures that limit effective collaboration with its academic affiliates” and included a decision tree describing the requirements for data transfer. According to this chart, de-identified data should be made accessible by VA to the requester without any external or internal review; data that are not de-identified, but that have informed consent and HIPPA authorization, should also be readily shared, if the research has been approved by an IRB. These more flexible policies, if implemented, would significantly improve data sharing.

Our research revealed that some policies on accessing, sharing, and storing research data are more restrictive at VA than at NIH. For example, while both agencies require that laptops and other mobile devices containing sensitive information are subject to FIPS 140-2 encryption, VA guidelines state that all removable storage that connects to VA computers must be encrypted.\(^{274,275}\) This rule requires that in order to store data outside of VA computers, regardless of these data sensitivity, the researchers must obtain VA-issued thumb drives. According to the research community, these devices are in short supply and do not work reliably outside of VA. As easily available non-encrypted memory sticks are not allowed for VA data storage, a simple task of taking non-sensitive data to be presented at a scientific conference...
becomes a real challenge at VA. Furthermore, the burden of distributing and keeping track of hundreds of encrypted thumb drives falls on OI&T.

**Problem Area 1c: Excessive training requirements**

Another strong theme that emerged from the survey of VA-funded researchers is excessive training requirements. For example, 55% of respondents disagreed or strongly disagreed with the statement that the amount of time spent on research-related training was appropriate, and 58% agreed or strongly agreed with the statement that the frequency of training in human subjects protection was too high. To understand the sources of the training requirements and the burden associated with them, we asked several ACOS to provide us with a list of training courses required at their facilities (no such document is available at ORD). Information that follows is based on the data from one VAMC with a large research program. We assume that the requirements are similar at other facilities.

**Burden and its sources.** The list of courses which we received included 58 items. Of these, 36 courses are required annually, 5 every two years, 1 every three years, and 15 once, at the time of hire (Exhibit 69A). Of 58 courses, 24 (41%) are required for all staff, 14 (24%) for clinicians, and 20 (34%) for some staff engaged in specific activities (Exhibit 69B). Based on this information it follows that at a minimum, each researcher must take 24 courses, many of them annually. Furthermore, at least half of VA-funded researchers are also clinicians (60% of survey respondents have clinical duties), and will have to take 14 additional courses, bringing the total number of courses for the majority of the research community to 38 (24 + 14). As most scientists work with human subjects, and/or animals, and/or radioactive materials, they would be required to complete specialized training in these areas as well.

**Exhibit 69. Training requirements**

<table>
<thead>
<tr>
<th>Frequency of training for all staff (N=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Once</td>
</tr>
<tr>
<td>Every 3 years</td>
</tr>
<tr>
<td>Every 2 years</td>
</tr>
<tr>
<td>Annually</td>
</tr>
</tbody>
</table>

Number of courses

<table>
<thead>
<tr>
<th>Frequency of training by type of staff (N=58)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some staff</td>
</tr>
<tr>
<td>Clinicians</td>
</tr>
<tr>
<td>All staff</td>
</tr>
</tbody>
</table>

Number of courses

*Source: Abt Associates.*
To further understand training burden, we examined the source of the requirements. It emerged that a third of the courses are mandated by the Joint Commission, an accreditor of health care organizations (Exhibit 70). For example:

- The environment of care (required for all clinicians annually)
- Medical radiation guide for safe usage (required for all clinicians annually)
- Prevention of patient falls (required for all clinicians annually)
- Anticoagulation education (required for all clinicians annually).

VA and VHA contribute 43% of training requirements (Exhibit 71), including:

- Awareness of patient abuse (required annually for all staff)
- Compliance and business integrity (required for all new employees and annually for clinicians)
- Confidentiality and public affairs (required once for clinicians)
- Prevention of workforce harassment (required for all staff every two years).

Note that while VA/VHA appears to be a source of many courses, it is highly likely that in some cases VA is simply following federal laws which mandate them. Courses in HIPPA and diversity in the workplace are some examples.

We found that the training required by the research program is a small fraction of the total – five courses or 9% (Exhibit 70). It includes:

- Human Subjects Protection and Good Clinical Practices (required for staff involved in human subjects research every two years)
- Working with the VA Institutional Animal Care and Use Committees (IACUC) plus species-specific courses, as appropriate (required annually for investigators working with animals)
- Biosafety (required annually for relevant staff)
- Radiation safety (required annually for relevant staff)
- General safety (required annually for all research staff and non-research staff involved in research).

**Exhibit 70. Sources of training requirements**

![Bar chart showing sources of training requirements]

Source: Abt Associates.
It is important to point out that most PIs at VA are affiliated with universities and are subject to the university training requirements, which may or may not duplicate VA requirements. We do not have the data to describe the magnitude of this additional training volume.

To standardize training and to reduce duplicative requirements ORD subscribes to the Collaborative Institutional Training Initiative or CITI. CITE offers numerous training courses related to the conduct of research, including modules on human subjects protection, animal protection, responsible conduct of research, health information privacy, and biosafety. Using CITI has several important benefits. First, CITI engages experts to review the content of the courses. Second, CITI learners answer “enrollment questions” that allow them to self-enroll based on their role(s) in research. For instance, if a learner indicates that he/she is engaged in animal research, the software adds the required coursework to their CITI account. Third, the software keeps track of the training expiration dates and reminds the users who are due to take the course (each organization can specify the frequency of training and the required coursework). Finally, researchers can link their CITI account to multiple institutions. The CITI system will track their progress in meeting each institution’s requirements and will give them credit for any overlapping coursework already taken. The main limitation of CITI is that an administrator responsible for training cannot assign courses to learners, a capability which is available in TMS, the training system currently used across VA.

While many training modules are available through CITI and VA can add other modules as necessary, the use of CITI-based training at VA is currently limited to a handful of courses in human subjects protections. The main obstacle to the wider use of CITI for research compliance training is a shortage of ORD staff. CITI could also be used for non-research training, but we were told that VA is committed to the TMS platform. ORD plans to implement CITI more widely and to integrate it with the Research Administration Management System (RAMS), which is now in development.

**Costs associated with compliance**

Because of the size of the VA research community, the costs associated with compliance are very high. While our study focused primarily on the approximately 2,000 ORD-funded PIs, the total number of PIs and staff conducting research at VA is estimated by ORD at 16,000. In addition to the VA-funded PIs this number includes approximately 2,000 ORD-funded research staff and 12,000 PIs and staff doing research at VAMCs, but not funded by ORD. We found in the survey of PIs that they spent, on average, 10% of their time on compliance-related activities. Assuming 2,080 hour year and an average hourly rate of $50, this translates into $41.6 million in costs for ORD-funded PIs and staff (208 * $50 * 4,000 = $41,600,000). As we did not survey non-ORD funded researchers, we do not know how much time they spent on compliance. However, these individuals are expected to be required to follow at least some of the VA requirements, including training, attainment of WoC appointments, getting access to equipment, and so on. Assuming that this group spends 5% of their time on compliance, the costs to VA are estimated at $62.4 million (104 * $50 * 12,000 = $62,400,000). The total cost for the entire research community is **$104 million per year** ($41.6M + $62.4M = $104M).

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277 Interview #57. December 2011.

278 Ibid.
Conclusions and recommendations

Our analysis revealed significant inefficiencies in IT, human subjects protections, and training processes. We suggest the following solutions.

- **Human subjects protection program.** To reduce burden on the research community without compromising Veteran safety, we suggest eliminating or simplifying most or all of the rules and regulations that are not required by Common Rule or other federal laws. In addition, VA should empower IRB to make all the decisions involving human subjects protections. Additional levels of oversight required by ORD weaken IRB’s authority and delay the initiation of research. We recommend shifting most or all of the decisions related to human subjects protection to IRB and omitting additional approval steps involving R&D Committees, POs, ISOs, and CRADO.

- **IT support.** Based on our analysis of VA documents, the PI survey, and interviews with OI&T we believe that VA should bring its IT-related policies more in line with the NIH intramural program. The first step in this process requires better understanding by IT staff of research data, processes, and needs, as well as greater awareness in the research community of OI&T constraints and the protections those constraints provide. This would go a long way to resolving existing problems. We believe that creating an ORD/OI&T liaison position may go a long way to improving the communication between these two organizations. Individuals in this position should begin their duties by reaching out to ORD and to the field to better understand their needs for software and hardware. Once this discussion has taken place, the OI&T liaison should clearly communicate to the research community what services and products the IT group can and cannot offer and why. We also suggest clearly stating in Handbook 6500 what types of research data are not sensitive using the NIH list as a starting point. Consequently, IT staff in the field would not have to use their own judgment to define the data and take responsibility for this decision. Finally, VA should revise its policies to allow the use of external devices for storage of non-sensitive data. The vast majority of presentations will not contain PII and do not need to be securely handled. Therefore, the default arrangement should be that this type of data can be stored on regular memory sticks. To safeguard sensitive information, OI&T should communicate to the research community what data must be stored on encrypted thumb drives.

- **Training.** Our analysis of training requirements at VA revealed that the number of courses that have to be taken annually by staff is very high. At a minimum, every researcher (and all other staff at VA) is required to take 16 courses a year (data not shown). All clinicians – half or more of the research community – are required to take an additional 11 courses every year. Finally, many researchers will have to take at least some specialized courses relevant to their work, such as training in animal or human subjects protection. In addition, the frequency of the trainings is unnecessarily high, many researchers are required to complete courses that are irrelevant to their duties, and there is no system in place to reduce duplication between VA and affiliate training.

We recommend reviewing all training courses currently required for the research community to determine which courses can be eliminated or required less frequently. Further, VA should develop a better system to identify which researchers need the training and whether those individuals already know the content of the course. Currently, the system is very inefficient and, as a result, many researchers are required to complete modules which are not relevant to their duties. The RAMS system currently under development at ORD, especially if linked to CITI, would be a significant improvement. A further improvement to the system would be to reduce the frequency of required training and to allow a learner to complete a quiz in the beginning of
the training session, to determine whether they need to go through the whole module. If not, they can receive credit for the course with minimal time investment.

We also recommend moving as many training courses as possibly into CITI. According to our informant, CITI is a superior system to what is currently in place at VA. This system is particularly appropriate for the ORD community, as many researchers have academic affiliations and are likely to be subject to duplicative training requirements resulting from dual appointments. The CITI system can keep track of and give credit for training already completed at another institution.

Finally, ORD should collaborate with the affiliates to develop a mechanism for researchers to get reciprocal credits for training courses taken either at VA or at the affiliate. We understand that some VAMCs have achieved this type of arrangement with their collaborating universities. More facilities should follow their example, in particular the sites which have close ties to major medical centers.

We realize that implementing these steps would require an initial investment from VA, to review the training requirements and to re-design the training system. However, we believe that given our estimates of training costs this investment will quickly pay off. In addition, eliminating unnecessary requirements will improve the level of satisfaction with VA among the researchers, clinicians, and affiliate collaborators.

Limitations of the approach

Our approach to the analysis of regulatory burden at VA had a few limitations. First, the estimates of costs associated with excessive regulation are imprecise. For example, we assumed PI salary at $50 an hour and training duration at 1 hour, which may be inaccurate. The estimates of time required to comply with all the requirements are also imprecise, especially for all subgroups which have not been surveyed during the study. Second, based on anecdotal evidence, there is some variability in the number and types of courses required at different VAMCs, and thus our list might not be representative of all facilities. Third, despite repeated efforts, we were unable to engage OI&T in the discussion of our findings and recommendations and thus cannot evaluate their feasibility.

Problem 2 – Resource Allocation

Given a potential reduction in funding for research in future years, what strategy should ORD use to allocate limited research funding to best meet the anticipated needs of Veterans over the next five years (2014–2019)?

We took a multi-step approach to answer this question. First, we assessed the relationship between research and health care expenditures at present to identify areas where research exceeds health care or vice versa. Second, using a variety of indicators we examined program performance by Service and by disease area, which represent two different options for funding allocation. Understanding differences between groups of researchers could help ORD determine how to allocate funding to maximize certain outcomes. Further, we took advantage of historical expenditures and demographic trends to uncover diseases and conditions that are already significantly contributing and/or are expected to contribute to health care costs in the future. ORD could potentially direct some research funding toward these areas to try and stem the rising costs and to develop better treatments for diseases affecting many Veterans, although research tends to increase, and not decrease costs of care. Finally, we interviewed senior administrators at NIH, DoD, USDA, CDC and the National Institute of
Standards and Technology (NIST) to learn how these agencies make decisions on the direction of their research programs. We believe that some of these approaches can be adopted by ORD for its strategic planning processes.

**The status quo**

The President’s budget for VA Medical and Prosthetics Research is estimated at $583 million for FY2013, a small increase over the previous year. In recent years, research funding has been allocated to the four Services as follows:

- 41.4% or $190M to Biomedical Service (BLRD)
- 19.6% or $90M to Clinical Service (CLRD)
- 19.0% or $87M to Health Services (HLRD)
- 20.0% or $92M to Rehabilitation Service (RRD)

Individual Services, in turn, make competitive awards to the VA research teams.

Strategies for distributing funding to the research community are developed by ORD, and are shaped by input from various sources, including Congress, Veteran service organizations, and other entities at VA. Once specific programs are designed, they are announced to the research community, which responds by submitting proposals (Exhibit 71). Based on the assessment of the proposals by internal and external experts (called peer reviewers), each Service makes its funding decisions. Typically, proposal technical merit outweighs all other award criteria, including mission relevance. As only the individuals who are employed at VA as at least 5/8th FTEs are eligible for funding, scientific directions that can be pursued by VA are limited by the interests of the research community and the quality of the applications submitted.

ORD uses several vehicles to disburse funding to its research community, including research grants (called “merit awards”), career development awards, and research Centers of Excellence. The amount and duration of funding vary by mechanism; there are also differences between Services in preferred award mechanisms and funding limits. Most research projects are funded for 4–5 years and further funding is awarded through competitive renewals. Renewal applications are subject to the same peer review process as new applications.

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280 Data provided by ORD.

281 Merit awards are similar to NIH R01 grants, career development awards to NIH K grants, and Centers of Excellence to NIH P grants.
To examine the soundness of the current funding strategy and to explore alternatives, we sought to answer the following questions:

- What is the relationship between research funding and Veteran needs today?
- How do various researcher groups perform on a range of metrics? Are there significant differences in performance between Services and disease focus areas?
- What will the Veteran needs be in the future? What funding strategies can VA use to better meet these needs?

To explore various approaches to the strategic planning and funding allocation process, we interviewed senior administrators at several federal agencies that support scientific research and a VA employee knowledgeable about the internal innovation initiative, VAi2. We asked these individuals how they make decisions on scientific priority areas and what tools they use to shape research portfolios. Our findings are described in the rest of this report.

**Relationship between research and health care expenditures at the time of study**

We began our analyses by examining to what extent VA research expenditures map onto health care expenditures. To make this comparison, we needed a coding scheme which would be suitable for categorizing both research projects and health care expenditure. We settled on ICD-9 codes, unique numbers assigned by health care providers to each disease/condition manifested by a patient in order to bill insurers for services rendered.

While VHA does not bill insurers, its clinicians nevertheless use ICD-9 codes to keep track of expenditures. We obtained from VA a dataset of ICD-9 expenditures for 2006–2011, which included information on the number of visits, patients, and inpatient/outpatient costs per year. The dataset
contained 1,024 codes, which can be grouped into 18 disease categories as shown in Exhibit 72. A few disease categories were subsequently excluded from the comparison, because:

- They were too general to classify as research projects (symptoms, signs, and ill-defined conditions [codes 780–799] and supplementary classification of factors influencing health status [codes v01-v89]).
- They referred to research with limited or no funding support at VA (complications of pregnancy, childbirth, and the puerperium [codes 630–679]; congenital anomalies [codes 740–759]; and certain conditions originating in the perinatal period [codes 760–779]).

**Exhibit 72. ICD-9 codes grouped into categories**

<table>
<thead>
<tr>
<th>Disease/condition</th>
<th>Code</th>
<th>Inclusion in comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious and parasitic diseases</td>
<td>001-139</td>
<td>Y</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>140-239</td>
<td>Y</td>
</tr>
<tr>
<td>Endocrine, nutritional, metabolic, and immune diseases</td>
<td>240-279</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the blood and blood-forming organs</td>
<td>280-289</td>
<td>Merged with circulatory</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>290-319</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the nervous system and sense organs</td>
<td>320-389</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the circulatory system</td>
<td>390-459</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the respiratory system</td>
<td>460-519</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the digestive system</td>
<td>520-579</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the genitourinary system</td>
<td>580-629</td>
<td>Y</td>
</tr>
<tr>
<td>Complications of pregnancy, childbirth, and the puerperium</td>
<td>630-679</td>
<td>N</td>
</tr>
<tr>
<td>Diseases of the skin and subcutaneous tissue</td>
<td>680-709</td>
<td>Y</td>
</tr>
<tr>
<td>Diseases of the musculoskeletal system and connective tissue</td>
<td>710-739</td>
<td>Y</td>
</tr>
<tr>
<td>Congenital anomalies</td>
<td>740-759</td>
<td>N</td>
</tr>
<tr>
<td>Certain conditions originating in the perinatal period</td>
<td>760-779</td>
<td>N</td>
</tr>
<tr>
<td>Symptoms, signs, and ill-defined conditions</td>
<td>780-799</td>
<td>N</td>
</tr>
<tr>
<td>Injury and poisoning</td>
<td>800-999</td>
<td>Y</td>
</tr>
<tr>
<td>Supplementary classification of factors influencing health status</td>
<td>V01-V89</td>
<td>V57* only</td>
</tr>
</tbody>
</table>

*V57 ICD-9 = Care involving use of rehabilitation procedures.  
Source: Allocation Resource Center, Department of Veterans Affairs.

Further, the “diseases of blood and blood forming organs” category, a small group of diseases containing mostly anemias, was merged with “diseases of the circulatory system.” Finally, from the generic group of codes called “supplementary classification of factors influencing health status” we included only V57, the code for rehabilitation. This code was merged with the “injury and poisoning” category. The process of merging and elimination resulted in 12 disease categories.

We examined the respective burden of each disease category on the health care system by analyzing costs and patient volume for FY2010 (data for FY2011 are provisional). Mental disorders, circulatory system, and musculoskeletal system emerged as the top three categories in expenditures and infectious disease, nervous system, and musculoskeletal system in number of patients (Exhibit 73). Similar results were obtained for FY2011 (data not shown).
The next step was to classify all research projects into the same 12 groups. To make the assignments as objective and systematic as possible, we used Web of Science (WoS), a well-regarded database of published research literature. The advantage of using WoS is that it classifies the articles returned in a search into research categories. WoS was queried using a combination of PI name in the author field and “Veterans affairs” in the address field. For example, if the query returned six articles, of which three were classified as “endocrinology and metabolism,” we assigned this PI to the “endocrine, nutritional and metabolic diseases, and immunity disorders” ICD-9 group. We used one-PI/one-category assignments to make subsequent analyses more straightforward.\textsuperscript{282}

It is important to note that many PIs affiliated with HSRD work on projects in quality of care/access to care, which cannot be coded using the ICD-9 system. To include as many of these researchers as possible, PIs who focus primarily on one disease were coded with the corresponding ICD-9. The rest were assigned to the “quality of care/care delivery” category and were subsequently excluded from comparisons between research and health care expenditures.

Exhibit 74 shows PI assignments to research areas. We were unable to code 3.6% of PIs (N=71) who did not appear to have a publication footprint. An additional 12.2% of PIs (N=240) were categorized into the “quality of care” group and 2% (N=46) were labeled “other.” For example, PIs specializing in magnetic resonance imaging or in surgery were in this last group. The figure shows that research in mental health dominates the ORD portfolio, with 16.3% of all researchers working in this area. The

\textsuperscript{282} Alternatively, PIs working in multiple areas can be given partial counts. We tested this approach in parallel and found that the results were similar.
quality of care group appeared large because it was used to group all HSRD projects that could not be assigned to a specific disease. Research on the diseases of circulatory and nervous system were third and fourth on the list, contributing 11.5% and 10.7% to the portfolio, respectively.

**Exhibit 74. Assignments of PIs to disease groups based on published literature**

<table>
<thead>
<tr>
<th>Disease Group</th>
<th>Percent PIs publishing on the subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>MENTAL DISORDERS</td>
<td>16.3</td>
</tr>
<tr>
<td>QUALITY OF CARE</td>
<td>12.2</td>
</tr>
<tr>
<td>NERVOUS SYSTEM AND SENSORY ORGANS</td>
<td>11.5</td>
</tr>
<tr>
<td>CIRCULATORY SYSTEM</td>
<td>10.7</td>
</tr>
<tr>
<td>INJURY, POISONING, REHABILITATION</td>
<td>7.7</td>
</tr>
<tr>
<td>NEOPLASMS</td>
<td>7.5</td>
</tr>
<tr>
<td>ENDOCRINE, METABOLIC, IMMUNITY</td>
<td>5.9</td>
</tr>
<tr>
<td>INFECTIOUS DISEASE</td>
<td>5.2</td>
</tr>
<tr>
<td>GENITOURINARY SYSTEM</td>
<td>4.4</td>
</tr>
<tr>
<td>MUSCULAR-SKELETAL</td>
<td>3.9</td>
</tr>
<tr>
<td>DIGESTIVE SYSTEM</td>
<td>3.8</td>
</tr>
<tr>
<td>RESPIRATORY SYSTEM</td>
<td>3.8</td>
</tr>
<tr>
<td>OTHER</td>
<td>2.3</td>
</tr>
<tr>
<td>SKIN</td>
<td>1.3</td>
</tr>
</tbody>
</table>

*Source: Abt Associates.*

N=1,896.

To compare research and health care expenditures, we calculated percentage of costs and patients versus percentage of PIs in each ICD-9 disease category. Our analysis included 83% of the research portfolio, 76% of patient volume, and 82% of health care expenditures due to exclusions of data described above. We found that for all disease categories the differences between research and patients/expenditures were small, within a few percentage points (Exhibit 75). The greatest discrepancy identified was for mental disorders, where research exceeded patient volume by 8.6 percentage points. However, even for mental health conditions percentages were similar when research was compared to expenditures. The expenditure data presented in Exhibit 6 are for 2010, but the differences were similarly small for 2011, although percentages for individual diseases and the direction of difference were not always consistent between the two years examined (data not shown).
Exhibit 75. Differences between research projects, patient volume, and health care expenditures

Program performance by Service

The stated mission of the VA research program is to “discover knowledge, develop researchers and health care leaders, and create innovations to advance health care for Veterans and the nation.” To measure program performance against this broad mission, we chose a set of 21 indicators that ranged from scientific productivity to quality of life. Some of these indicators are routinely used by evaluators to assess research and translational outcomes, such as publications and submissions for FDA approval, respectively. Others were developed in collaboration with the ORD leadership to capture the unique nature of the VA research program. The full list of indicators used in the study is shown in Exhibit 76.
Performance indicators were collected using three methods: abstraction from Web of Science, abstraction from Reporter, and the survey of ORD-funded PIs. Number of publications, citations, and impact factors were obtained from Web of Science using researcher name and VA affiliation as queries. The search was constrained to three years, 2008–2010. Note that publications which did not cite VA would be excluded in this search, but specifying affiliation was necessary to eliminate “false positive” hits that would be inevitable for researchers with common names. Thus, the average number of publications per year (approximately 2) is likely to be an underestimate. Each publication retrieved from Web of Science included statistics on the number of times it was cited by other papers (excluding self-citations) and the impact factor for the journal in which it was published. Using these data, we calculated average publication counts per year, average citation counts, and average impact factors.

As the research program budget is relatively small ($580 million compared to $30 billion at NIH), the ability of PIs to obtain funding from other sources is critical to sustaining their scientific programs. Furthermore, due to the highly competitive nature of extramural research funding, only very good proposals are selected by peer reviewers. Thus, ability to successfully apply for grants from other funders is an endorsement of VA research by the research community. For these two reasons we included extramural funding as a performance measure. To obtain data on extramural funding, we used the Reporter public database maintained by NIH, which includes information on the projects funded by NIH, AHRQ, the Health Resources and Services Administration (HRSA), CDC, the Substance Abuse & Mental Health Services Administration (SAMHSA), and VA. To examine the level of success of VA researchers in applying for extramural funding, we abstracted all grants that were active in 2010 and matched investigator names listed on these grants against VA PIs. We suspect that funding data for non-NIH grants are incomplete, as only a very small number of hits came up in the search.

All other outcome data listed in Exhibit 76 were collected in the survey of VA-funded PIs conducted in the summer of 2011. Survey respondents were asked to indicate whether various outcomes resulted from their research and the number of individuals responding in the affirmative was counted.

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284 Citation counts are dependent on the amount of time elapsed since the paper was published.

285 The impact factor of a journal is the average number of citations received per paper published in that journal during the two preceding years. Impact factors range from nearly 0 to approximately 53. Approximately 10% of journals do not have impact factors.

## Exhibit 76. Measures of research program performance

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Source of data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scientific productivity and reputation</strong></td>
<td></td>
</tr>
<tr>
<td>Number of publications per year</td>
<td>Web of Science</td>
</tr>
<tr>
<td>Number of citations</td>
<td>Web of Science</td>
</tr>
<tr>
<td>Impact factors</td>
<td>Web of Science</td>
</tr>
<tr>
<td><strong>Research sustainability</strong></td>
<td></td>
</tr>
<tr>
<td>Active extramural funding in calendar year 2010</td>
<td>NIH Reporter database</td>
</tr>
<tr>
<td><strong>Discovery of knowledge</strong></td>
<td></td>
</tr>
<tr>
<td>Research resulted in improved understanding of disease mechanism</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in identification of unknown side effects</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td><strong>Translation from bench to bedside</strong></td>
<td></td>
</tr>
<tr>
<td>Research resulted in FDA submission or decision not to submit</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in clinical trial</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td><strong>Clinical</strong></td>
<td></td>
</tr>
<tr>
<td>Percent time at VA spent on clinical duties</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in use of new drug, drug regimen, or novel treatment</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in new screening or testing approaches</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in better patient education</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in better provider education</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in development of new devices for Veterans</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in ways health care is delivered to Veterans</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in new/expanded disease management approaches</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in reduction in health care costs</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td><strong>Quality of life</strong></td>
<td></td>
</tr>
<tr>
<td>Research resulted in improvements in life expectancy</td>
<td>Survey of VA researchers</td>
</tr>
<tr>
<td>Research resulted in improvements in quality of life</td>
<td>Survey of VA researchers</td>
</tr>
</tbody>
</table>

*Source: Abt Associates.*

In order to optimize certain outcomes, it is necessary to have the information on how the groups differ on these outcomes. For example, if ORD wishes to maximize the number of publications resulting from the research program, it should direct its support to those groups that have the highest publication output. To maximize the number of devices developed for Veterans, support should be directed to the groups that excel in that area. We examined differences in performance between Services and between disease areas, two potential research allocation strategies.
It is important to consider the mission of each Service before comparing their outcomes, as the Services should perform best in the areas that are relevant to their stated goals, but not necessarily in the areas that are not what they have set out to accomplish. The focus of each Service, described on the ORD website, is as follows:287

- **BLRD** supports research exploring biological or physiological principles in humans or animals. For example, BLRD research includes pre-clinical models and investigations of tissues, blood or other biologic specimens from humans.

- **CSRD** supports research focusing on intact human beings as the unit of examination. Examples include interventional and effectiveness studies, clinical, epidemiological and technological studies.

- **HSRD** works to identify and evaluate innovative strategies that lead to accessible, high quality, cost-effective care for Veterans and the nation.

- **RRD** focuses on improving the quality of life of impaired and disabled Veterans.

Exhibit 77 presents outcomes across Services, with the numerical values showing the averages for PIs in each Service as well as for the whole program. In dark color are the Services that performed significantly better than program average and in light color significantly worse than program average, using the significance cutoff of p<0.01. No color indicates that performance for this group was not significantly different from the average across groups.

We observed that the strengths and weaknesses of each Service were consistent with its mission and research focus. The following noteworthy trends emerged:

- **BLRD** was better than average in discovery of knowledge, and sustainability (as measured by extramural funding).

- **CSRD** was better than average in discovery of knowledge, translation, use of new drugs/treatments, hours spent on clinical duties, and improving life expectancy.

- **HSRD** was better than average in productivity (as measured by the number of publications), provider education, and changes in health care delivery.

- **RRD** was better than average in making devices for Veterans and improving their quality of life.

287  [http://www.research.va.gov/default.cfm](http://www.research.va.gov/default.cfm)
Exhibit 77. Outcome differences between Services

Dark color indicated above average and light color below average performance

<table>
<thead>
<tr>
<th>Scientific productivity and reputation</th>
<th>BLRD</th>
<th>CSRD</th>
<th>HSRD</th>
<th>RRD</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of publications per year(a)</td>
<td>2.1</td>
<td>2.0</td>
<td>1.7</td>
<td>1.6</td>
<td>2.2</td>
</tr>
<tr>
<td>2. Number of citations(b)</td>
<td>9.1</td>
<td>11.3</td>
<td>6.7</td>
<td>8.1</td>
<td>8.1</td>
</tr>
<tr>
<td>3. Impact factor(b)</td>
<td>5.6</td>
<td>6.1</td>
<td>4.9</td>
<td>5.2</td>
<td>5.2</td>
</tr>
</tbody>
</table>

| Research sustainability                 |      |      |      |     |         |
| 4. Active extramural funding(c)         |      |      |      |     | 14.5    |
| 5. 75-99% of funding comes from ORD(c)  |      |      |      |     | 21.8    |
| 6. 100% of funding comes from ORD(c)    |      |      |      |     | 16.2    |

| Discovery of knowledge                  |      |      |      |     |         |
| 7. Understanding disease mechanism(c)   |      |      |      |     | 58.6    |
| 8. Identification of side effects(c)    |      |      |      |     | 11.4    |

| Translation from bench to bedside       |      |      |      |     |         |
| 9. FDA submission(c)                    | No data |      |      |     | 8.9     |
| 10. Clinical trials(c)                  | No data |      |      |     | 56.9    |

| Clinical                                |      |      |      |     |         |
| 11. Hours per week spent on clinical duties(c) | 5.2 | 6.3 |      |     |         |
| 12. Use of new drug or treatment(c)      | No data |      |      |     | 35.8    |
| 13. New testing or screening approaches(c) | No data | 35.4 | 32.8 | 41.5 | 35.3 |
| 14. Better patient education(c)          | No data | 43.4 | 49.7 | 52.8 | 48.4 |
| 15. Better provider education(c)         | No data |      | 54.5 | 55.6 |      |
| 16. Changes in health care delivery(c)   | No data |      |      |     | 47.7    |
| 17. New disease management approaches(c) | No data | 47.0 | 48.8 | 48.4 | 48.2 |
| 18. Reduction in health care costs(c)    | No data | 32.4 | 34.1 | 26.0 | 31.9 |
| 19. New devices for Veterans(c)          | No data | 4.4 |      |     | 8.2     |

| Quality of life                          |      |      |      |     |         |
| 20. Improvements in quality of life(c)   | No data | 55.7 | 55.3 |     | 59.8    |
| 21. Improvements in life expectancy(c)   | No data |      | 12.6 | 8.2  | 15.5    |

Program performance by disease focus

We also examined the 21 program outcomes by disease focus. The analyses were similar to what was described in the previous section, except in this case PIs were assigned to 12 ICD-9 disease areas rather than four Services. We found that this approach did not reveal many trends between diseases (data not shown). There are several reasons for this. First, because we are using 12 instead of 4 categories, the sample size for each category is smaller. Second, we expect that researchers with the same disease
focus are affiliated with different Services, potentially blurring the differences in performance. For example, a researcher working on the biology of blindness will be based in BLRD, and a researcher working on visual prosthetics in RRD. These two researchers are likely to excel on different outcomes: BLRD researcher in contributing to the understanding of disease mechanism and RRD researcher in making devices for Veterans. When these researchers are assigned by Service, the differences in performance between them will be revealed, but when they are grouped into one disease, their performance indicators will be averaged and masked.

That said, the scheme did capture some variation:

- Researchers working on mental disorders were underperforming in research reputation, sustainability, and discovery of knowledge
- Researchers working in injury were underperforming in research reputation
- Cancer research and endocrine research were best funded
- Researchers in infectious disease scored best on provider education
- Researchers in injury/rehabilitation scored best on devices
- Researchers in endocrine and respiratory diseases scored best on understanding disease mechanisms.

Future health care needs of Veterans

While the VA research program is well aligned with health care expenditures at present, understanding future needs of Veterans might help ORD plan new programs. Note that it is very difficult to accurately predict Veteran needs and many economic and societal changes can have an effect on these predictions. Nevertheless, we attempted to forecast future health care needs by analyzing trends in ICD-9 codes and demographic projections, two sources of data available to us. Our analysis was aimed at identifying the diagnoses with likely higher future costs either because of recent trends in costs and patient volume or because the proportion of patients with these diagnoses is on an upward trend. We used the following data sources to analyze trends:

- County enrollment counts for 2006–2036 by gender and age from VetPop2007, the VA's latest official projection set of the Veteran population.
- VA patient counts and costs by ICD-9 codes for 2005–2011. Data included the number of patients and patient visits and inpatient/outpatient expenditure volumes.

Full datasets generated for this study are included in the appendix. In the next few sections, we describe the following analyses: (1) Veteran enrollment trends by age and gender; (2) disease prevalence for Veteran groups predicted to grow over time; (3) health care expenditures for all Veterans and the diseases that drive them; and (4) trends in Veteran homelessness and unemployment.

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Demographic trends. We found that the number of Veterans is expected to decline steadily over the next 20 years, from an estimated 23 million in 2010 to 14 million by 2040 (Exhibit 78A). This projected trend, however, is not uniform across demographic groups. In particular, enrollment of elderly and women Veterans is expected to significantly increase over time: from 21% in 2010 to 26% in 2036 for Veterans aged 75 and older and from 10% in 2010 to 18% in 2040 for women (Exhibit 78B and C). Other factors unchanged, these trends can be predicted to result in increases in patient volume and/or costs for diagnoses that are disproportionately high in these patient groups.

Exhibit 78. Projected enrollment and demographic changes at VA
We next examined ICD-9 data for conditions most prevalent in women and elderly Veterans for 2009–2011. Exhibit 79 shows that diseases for which at least 30% of patients were elderly included cancer and diseases of the blood, circulatory, and nervous systems. Other than women’s health conditions, such as complications of pregnancy, only infectious disease stood out as having significant numbers of female patients (22%).

**Exhibit 79. Disease prevalence for women and elderly, 2009–2011**

*Source: Allocation Resource Center, Department of Veterans Affairs.*

Women’s health includes complications of pregnancy and conditions originating in perinatal period.
To identify specific diseases prevalent in the elderly utilizing VA health care services, we examined recent ICD-9 data for the highest number of patients aged 75+. Exhibit 80 shows seven diseases in the elderly for which the number of patients exceeded 100,000 in 2010 (cost data were not available). The diseases fell into three categories: circulatory system, nervous system, and endocrine system.

Exhibit 80. Most common diagnoses among Veterans 75 or older, FY2010

<table>
<thead>
<tr>
<th>ICD-9 code</th>
<th>Disease category</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>401</td>
<td>Hypertension</td>
<td>471,756</td>
</tr>
<tr>
<td>250</td>
<td>Diabetes</td>
<td>262,970</td>
</tr>
<tr>
<td>389</td>
<td>Hearing loss</td>
<td>236,476</td>
</tr>
<tr>
<td>414</td>
<td>Ischemic heart disease</td>
<td>176,240</td>
</tr>
<tr>
<td>272</td>
<td>Disorders of lipoid metabolism</td>
<td>140,921</td>
</tr>
<tr>
<td>427</td>
<td>Cardiac dysrhythmias</td>
<td>100,830</td>
</tr>
<tr>
<td>365</td>
<td>Glaucoma</td>
<td>100,233</td>
</tr>
</tbody>
</table>

Source: Allocation Resource Center, Department of Veterans Affairs.

Health care costs and patient volume. VA provided us with a dataset which included the number of Veteran patients and visits as well as inpatient and outpatient expenditures by ICD-9 codes for the past seven years (the set included over 1,000 codes). We analyzed these data for trends. Exhibit 81 shows all diseases with more than $500,000 in 2010 expenditures, excluding three catch-all “other” codes. Dominating the list were mental health conditions (substance abuse, PTSD, schizophrenia, psychotic conditions) and diseases of the circulatory system (ischemic heart disease, hypertension, and cerebrovascular disease).

Exhibit 81. Diagnoses with expenditures exceeding $500,000 in 2010 (data sorted by cost)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Disease category</th>
<th>Cost</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic heart disease</td>
<td>Circulatory system</td>
<td>$1,102,725,003</td>
<td>461,035</td>
</tr>
<tr>
<td>Substance abuse disorder</td>
<td>Mental disorders</td>
<td>$1,077,752,556</td>
<td>348,725</td>
</tr>
<tr>
<td>PTSD</td>
<td>Mental disorders</td>
<td>$1,032,571,904</td>
<td>543,184</td>
</tr>
<tr>
<td>Nephrotic conditions</td>
<td>Genitourinary system</td>
<td>$1,017,645,520</td>
<td>122,082</td>
</tr>
<tr>
<td>Arthropathies (diseases of joints)</td>
<td>Musculoskeletal system</td>
<td>$973,361,122</td>
<td>908,087</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Endocrine system</td>
<td>$883,488,883</td>
<td>1,004,451</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>Mental disorders</td>
<td>$864,331,121</td>
<td>325,693</td>
</tr>
</tbody>
</table>
### Exhibit 82. Drivers of health care costs, 2005–2011

<table>
<thead>
<tr>
<th>Disease category</th>
<th>Disease</th>
<th>Cost</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental disorders</td>
<td>Organic psychotic conditions</td>
<td>$806,218,975</td>
<td>165,840</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>Schizophrenia</td>
<td>$877,776,350</td>
<td>83,133</td>
</tr>
<tr>
<td>Circulatory system</td>
<td>Hypertension</td>
<td>$801,606,874</td>
<td>1,626,862</td>
</tr>
<tr>
<td>Musculoskeletal system</td>
<td>Dorsopathies (diseases of back and spine)</td>
<td>$796,787,385</td>
<td>722,465</td>
</tr>
<tr>
<td>Nervous system</td>
<td>Eye disorders</td>
<td>$715,178,581</td>
<td>1,191,864</td>
</tr>
<tr>
<td>Digestive system</td>
<td>Oral disease</td>
<td>$631,245,686</td>
<td>435,966</td>
</tr>
<tr>
<td>Circulatory system</td>
<td>Cerebrovascular disease</td>
<td>$597,485,660</td>
<td>144,509</td>
</tr>
<tr>
<td>Respiratory system</td>
<td>Chronic obstructive pulmonary disease (COPD)</td>
<td>$548,833,462</td>
<td>374,158</td>
</tr>
</tbody>
</table>

**Source:** Allocation Resource Center, Department of Veterans Affairs.

Between 2005 and 2011, total health care costs have grown from approximately $22 to $34 billion, an increase of 53% (data not shown). Using ICD-9 data, we examined cost drivers – diseases and conditions with the largest increases during this period (catch-all codes were excluded from the analysis). Exhibit 82 shows top 11 cost drivers, which account for a third of the increases in the past 6 years. Diseases of cardiovascular system and mental health conditions were again most common.

Dorsopathies are diseases of back and spine.
Next, we examined the data for Veteran diseases and conditions which showed the largest increases in average cost per patient and in the number of patients over the past seven years (costs were not adjusted for inflation). The cost per patient for the following 10 conditions has increased by more than 50%:

- Complications of pregnancy (350% increase, from $763 to $3,438)
- Heart valve disease (94% increase, from $1,788 to $3,468)
- Inflammatory disease of the central nervous system (78% increase, from $1,788 to $3,468)
- Cerebrovascular disease (64% increase, from $2,581 to $4,237)
- Nephrotic conditions (61% increase, from $4,858 to $7,819)
- Paralytic syndromes (59% increase, from $8,895 to $14,174)
- Arthropathies (59% increase, from $672 to $1,070)
- Atherosclerosis/arterial disease (56% increase, from $1,893 to $2,952)
- Vein and lymphatic disease (52% increase, from $995 to $1,512)
- Osteopathies (51% increase, from $1,021 to $1,538).

Of these conditions, four fall in the diseases of circulatory system, two of nervous system, and two of musculoskeletal system.

We also identified seven conditions which increased in the number of patients by at least 50% since 2006. These were as follows:

- Organic sleep disorders (367% increase, from 23,812 to 111,116 patients)
- Nutritional deficiency (101% increase, form 34,119 to 68,605 patients)
- PTSD (69% increase, from 348,101 to 587,051 patients)
- Endocrine gland disease (69% increase, from 39,507 to 66,613 patients)
- Complications of pregnancy (60% increase, from 4,296 to 6,889 patients)
- Bipolar disorder (60% increase, from 228,368 to 343,006 patients)
- Nephrotic conditions (53% increase, from 85,057 to 129,701)

Of the seven, two were mental disorders and two endocrine disorders. Full datasets are included in the appendix.

Growing homelessness and unemployment among Veterans are widely reported in the press (for example, “At War,” The New York Times, Feb 6, 2012). We noticed that ICD-9 classification includes codes for homelessness (V60) and unemployment (V62) and examined trends for these two conditions between 2005 and 2011. We found that homelessness has indeed increased by 77% and unemployment by 82% over this time period (Exhibit 83). Given these alarming trends, ORD could direct some funding to support research on strategies to help Veterans’ re-integration into society.
Strategic planning processes used by other federal agencies

To identify potentially applicable strategic planning approaches not currently used by ORD, we interviewed representatives from several federal agencies that sponsor scientific research, including the National Institutes of Health (NIH), the National Institute of Standards and Technology (NIST), the United States Department of Agriculture (USDA), and the Department of Defense. In addition, we spoke with the individual knowledgeable about the VA Innovation Initiative (VAi2), as this program uses different strategies to identify and fund projects. The list of organizations is shown in Exhibits 16. Interviewees were asked to describe how funding priorities are established in their organizations and what tools they have to shape their portfolios of projects. Information for each agency is summarized in Exhibit 84. ORD was included for comparison purposes.

Exhibit 84. Summary of information on the organizations included in the study

<table>
<thead>
<tr>
<th>Organization</th>
<th>Budget for FY2012</th>
<th>Nature of the program</th>
<th>Type of proposal review</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIBIB</td>
<td>$322M</td>
<td>Extramural &amp; intramural</td>
<td>External peer reviewers</td>
</tr>
<tr>
<td>NIST Lab Program</td>
<td>$567M</td>
<td>Intramural</td>
<td>NIST staff</td>
</tr>
<tr>
<td>NIFA</td>
<td>$710M</td>
<td>Extramural</td>
<td>External peer reviewers</td>
</tr>
<tr>
<td>CDMRP</td>
<td>$537M(a)</td>
<td>Extramural</td>
<td>External peer reviewers</td>
</tr>
<tr>
<td>DARPA</td>
<td>$3B</td>
<td>Extramural</td>
<td>DARPA staff</td>
</tr>
<tr>
<td>VAi2</td>
<td>$103M(a)</td>
<td>Extramural &amp; intramural</td>
<td>VA staff</td>
</tr>
<tr>
<td>ORD</td>
<td>$581M</td>
<td>Intramural</td>
<td>External and internal peer reviewers</td>
</tr>
</tbody>
</table>

(a) Budget for FY2011.
National Institute of Biomedical Imaging and Bioengineering (NIBIB). At NIBIB (and at other NIH institutes), funding priorities are described in the strategic plan. The Institute just completed its strategic planning process, which included several phases. In the first phase, all division heads and the Institute director re-examined the mission of NIBIB to ensure that it was consistent with their Congressional mandate and reflective of current research opportunities. These initial discussions occurred over several all-day meetings with the assistance of professional facilitators. Many opinions were expressed about scientific opportunities and challenges, directions of scientific research, the NIBIB mission, and its position within NIH. In addition to these meetings, the leadership group consulted with other NIH institutes and federal agencies. This process resulted in a list of priority areas, which was presented to the NIBIB Advisory Council.

By law, every NIH institute is required to have an Advisory Council, a group of approximately 12 individuals which meets three times a year. The initial NIBIB list of priority areas was discussed over 2–3 closed Council sessions (only Council members present) before being presented at the open session (accessible to the public). According to our informant, the institute got helpful feedback from the Council about revising some priority areas and adding others. The list was then posted on the internet for input from the research community. Many comments were received and discussed by the institute’s leadership, and the list was again revised and presented to the Council. Once approved by the Council, these priorities were used to craft the strategic plan. The NIBIB website contains a list of approximately 20 focus areas that emerged from this process. Like other NIH institutes, NIBIB does not attach specific dollar amounts to its priority areas.

NIBIB can shape its research portfolio using several mechanisms. As is the case with other NIH institutes, the bulk of the NIBIB budget, approximately 70%, is spent on the research projects conceived and carried out by scientists outside of NIH. To receive funding from NIH, extramural researchers develop funding proposals which are submitted to the Center for Scientific Review, the branch of NIH responsible for arranging and managing the peer review process. Based primarily on scores from peer reviewers, NIH institutes make funding decisions, which must be approved by their Advisory Councils. Since the number of meritorious proposals usually exceeds the number of awards that can be made, each institute has some flexibility to choose projects that best align with its mission. Furthermore, the NIH institutes can convey to the research community what their priorities are by posting strategic plans and areas of interest. Finally, the institutes can put together their own review panels or give instructions to the study sections convened by the Center for Scientific Review, thus shaping the review process. However, the choices of research directions for extramural projects are constrained by the interests of the research community applying for funding.

About 10% of NIBIB funding is spent on the Requests for Applications (RFAs). These are funding opportunities issued by the NIH institutes to support research in specific areas. While the application and review process for RFAs is similar to that for investigator-initiated research, RFAs direct research support to a narrower set of scientific problems of interest to the funding institute. Thus, RFAs are more efficient tools for direction setting, but they represent only a small fraction of the institutes’ budgets.

Like most other NIH institutes, NIBIB has an intramural program, which can be used to shape the institute’s portfolio through hiring of researchers with desired expertise. However, because NIBIB is a young institute by NIH standards (it was founded in 2000), it has a small intramural program, composed of four groups with the total funding of 3–4% of the NIBIB budget. At other institutes, the intramural research budget rarely exceeds 10% and therefore, it represents a small fraction of the institutes’
research portfolio. We were also told that it is difficult to grow the intramural program during times of fiscal austerity, so opportunities for changing direction using this mechanism are also limited.

Finally, the NIH institutes can expand their portfolios by partnering with each other on funding opportunities. For example, NIBIB collaborates with the Institute for Child Health and Development and the National Institute for Neurological Disorders and Stroke to fund a program in rehabilitation research.

**National Institute of Standards and Technology (NIST).** The mission of NIST is to “promote US innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve quality of life.” As this mission does not emphasize any particular sector, the leadership of NIST must continuously interpret the organization’s mandate to make research investment choices. These choices are influenced by various groups. In some cases, Congressional guidance accompanies funding appropriations. For example, in the last fiscal year NIST’s budget was increased by $70 million, of which $25.5 million was directed by Congress toward research in cybersecurity. In addition, other government agencies (such as EPA and FDA), industry, and the research community offer opinions through formal and informal channels. The recently launched external needs assessment workshop series, for instance, is intended to systematically solicit stakeholder input to inform NIST strategic decisions.

NIST also relies on several technical boards for guidance. Members of the boards, who are appointed by the NIST director, help interpret the organization’s mission and identify areas of emphasis. For example, the Visiting Committee on Advanced Technology (VCAT) advises NIST leaders on strategic planning, policies, budget, performance, and programs. VCAT members are typically chosen from among the top echelons of industry and academia, and include university deans, presidents, and chief executive officers at large companies. One of the responsibilities of VCAT is to produce annual reports to Congress. The 2010 VCAT report, for example, describes its findings on the role of NIST in supporting industrial innovation and competitiveness and its views on NIST reorganization. Finally, performance of NIST laboratories is periodically evaluated by the National Research Council and the recommendations are used to inform the strategic planning process.

Based on this input, funding priorities are established annually by a small group of senior NIST administrators, composed of the director, associate directors, and six laboratory heads. In the fall, the group coalesces around investment decisions, although funding reallocations between the laboratories occur throughout the year. NIST is a fairly stable organization. It recently underwent its first reorganization since 1988 to improve the alignment between NIST laboratories and the agency’s mission.

NIST uses several tools to shape its investment portfolio. First, the composition of the intramural community can be directed toward particular research areas through hiring. For example, some years ago the decision was made to boost the NIST biotechnology program, resulting in increased hiring of biologists, who typically enter NIST as postdoctoral fellows. Another tool for research allocation used by NIST is internal re-programming, whereby various programs are moved around, built up (through additional requests to Congress), or terminated. NIST also sponsors annual bottom-up competitions, which can drive the direction of projects and areas of expertise. In some cases, changes occur in the NIST research portfolio, which are outside of its leadership’s control. For example, last year two of the

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NIST programs lost federal funding. The Baldridge Program\(^{290}\) will be sustained for another year through endowment, but the Technology Innovation program\(^{291}\) has already been terminated.

**National Institute of Food and Agriculture (NIFA).** Created in 2008, NIFA is one of four research and development entities within USDA. NIFA’s mission is to advance knowledge in agriculture, the environment, and human health by providing competitive funding to land grant,\(^{292}\) state, and private universities. Following reorganization in 2008, the NIFA directorship became a political appointment and its focus was narrowed to five challenge areas: food safety, climate change, food security, sustainable energy, and childhood obesity. NIFA’s research program is extramural.

Funding for NIFA is appropriated in the Farm Bill. For some of its programs, NIFA receives extensive guidance from Congress, leaving little flexibility in the setting of scientific direction. One of the less prescriptive programs is called the Agriculture and Food Research Institute (AFRI). AFRI is NIFA’s largest and most competitive program, with a budget of $260 million per year (almost 40% of NIFA’s total budget). In the recent AFRI appropriation, Congress laid out six broad focus areas, leaving NIFA with some flexibility to support specific lines of research within this broader guidance.

NIFA managers try to incorporate input from scientific societies and producer groups, its key stakeholders, when making strategic decisions. This input is provided through numerous unsolicited emails and occasional public meetings, for which invitations are published in the federal register. Our informant noted that it is somewhat challenging to use stakeholder input, because the needs are not prioritized and the budget is limited. Stakeholder input is nevertheless considered as much as possible and is presented as a summary in the requests for proposals. Program direction is heavily influenced by Project Managers, who are experts in their fields, and is shaped by the NIH-style peer review process.

While NIFA is prohibited from lobbying Congress, program managers try to educate Congress about NIFA’s research needs by carefully crafting responses to Congressional queries. Further, the Farm Bill is reauthorized every 5 years, in principle offering USDA an opportunity to make strategic changes. However, while in the past Congress solicited ideas for new programs from USDA, this has not happened recently. Our respondent commented that in the climate of budget cuts most agencies “do not want to rock the boat,” and concur with Congressional decisions.

NIFA has not historically had a robust evaluation process. Project managers carry out ad hoc portfolio analyses, but these activities were not seen by our informant as especially useful for strategic planning.

**Congressionally Directed Medical Research Program (CDMRP).** Established in 1992 at the urging of breast cancer advocacy groups, CDMRP now supports research on 28 different diseases and conditions; its budget for FY2011 was $537 million (a list of funded areas is included in the appendix).\(^{293}\) All

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\(^{290}\) The mission of the Baldridge Program is to “improve the competitiveness and performance of U.S. organizations for the benefit of all U.S. residents” (http://www.nist.gov/baldrige/about/index.cfm).

\(^{291}\) The mission of the Technology Innovation Program is to “support, promote, and accelerate innovation in the United States through high-risk, high-reward research in areas of critical national need” (http://www.nist.gov/tip/).

\(^{292}\) Land-grant universities are institutions of higher education established by the Morrill Acts of 1862 and 1890. The Act granted federally controlled land to the states to establish and endow "land-grant" colleges, which would focus on the teaching of practical agriculture, science and engineering.

\(^{293}\) Congressionally Directed Medical Research Programs. 2011 Annual Report.
research supported by CDMRP is extramural. The nature of the diseases chosen for research support and the amount of funding allocated per disease is determined by Congress and is influenced by lobbying. CDMRP funds are not included in the President’s budget, but added by Congress to the DoD appropriation. The level of guidance originating from Congress varies: in some cases only the amount of funding per disease is specified and in others a disease might be accompanied by a list of 10–15 specific topics to be funded.

Each of the 28 programs is focused either on one disease (breast or lung cancer) or on a group of related conditions (women's health). The proportion of funding for a given program is usually stable over time, although fluctuations do occur, including complete de-funding of certain diseases. For example, the prion program has been discontinued. CDMRP does not have the authority to re-allocate funding between programs/diseases and the funding must be disbursed within two years. These requirements and the dependence of the budget on lobbying make program management somewhat challenging. For example, portfolio managers have to hold two or more funding competitions per year, to ensure that they receive enough high quality proposals. Each program is managed by 40–50 people, who are responsible for identifying appropriate funding mechanisms, peer review process, and award monitoring.

When a new program is initiated by Congress, CDMRP engages in a two-phase strategic planning process. The first phase is called a “stakeholder meeting.” The goal of the meeting is to survey the scientific landscape and identify research goals, gaps and opportunities. At this stage, CDMRP casts a wide net, inviting dozens of researchers, clinicians, consumers (persons affected by the condition or their relatives), advocates, and representatives from other federal agencies. The size of the stakeholder group varies. For example, the Duchene atrophy program invited 20 stakeholders and the orthopedics program 80–90 people. All input is taken, but no decisions are made during stakeholder meeting.

The second phase of the process – “vision setting” – involves a much smaller group of participants, approximately 8 to 18 individuals, also chosen from among clinicians, researchers, and advocates. This group is called the Integration Panel. The Panel meets annually (or immediately after the stakeholder meeting for new programs) and is responsible for developing individual investment strategies for each program. The products of the vision setting are program announcements, which communicate funding opportunities to the research community. Proposals submitted in response to these announcements undergo peer review. An interesting aspect of the review process at CMDRP is that the last stage of the review – after the most meritorious applications have been selected – is performed by the same Integration Panel that defined that program’s vision.

As the set of diseases to fund and funding levels for each disease are decided by Congress, the main tools that CMDRP has to influence the direction of research include identifying participants for the stakeholder and vision setting processes and choosing funding mechanisms for specific programs. CMDRP rarely terminates grants (<1% of cases), but can halt funding if the project is not making sufficient progress. For instance, research funding is sometimes frozen until enough subjects are recruited by grantees for clinical trial.

**Defense Advanced Research Projects Agency (DARPA).** DARPA is an R&D arm of the Department of Defense. According to the DARPA’s website, it “takes on projects that are finite in duration but that create lasting revolutionary change.” DARPA is different from traditional extramural funding agencies like NIH or NSF in several important ways. First, it does not support investigator-initiated research. Ideas for projects originate primarily from DARPA staff. Further, research is funded through contracts, not grants, giving DARPA much more control over projects. Finally, DARPA does not support incremental research, but rather seeks extremely challenging, but potentially high impact ideas.
Examples of projects given to us by the DARPA project manager included creating a modular arm or developing new mathematical and statistical constructs to describe biological processes. DARPA has a high tolerance for failure, which was described to us as instrumental to its success. The expectation at DARPA is that projects will meet their stated goals less than 20% of the time.

DARPA program managers play a key role in shaping its research portfolio. This is a group of 100 (usually) civilian researchers hired on 3-year contracts. Program managers initiate project ideas and are evaluated based on these ideas; individuals who do not generate anything considered worthwhile by DARPA within their first year are terminated. Especially creative program managers are allowed to stay for another three years, but generally DARPA maintains that its staff runs out of ideas after their first term. The program manager we interviewed said that occasionally the research community or other federal agencies reach out to DARPA with ideas and that this input is welcome.

Once the idea is generated by a program manager, several extramural teams are invited to submit proposals. From among these, DARPA program managers choose the proposal that has the highest chance of success. Final selection of awardees is made by the DARPA director. Projects are usually funded at the $1 million level, which is seen by DARPA as a reasonable compromise between “having too much money not to care about it and enough to do the work without worrying about it.” Some winning team members change in the course of the project and DARPA program managers reserve the right to suggest additional members to bring on board. DARPA funds projects through contracts, and views researchers as having a fiduciary duty to follow project managers’ direction. DARPA’s contracts can be terminated at any time for any reason and, according to the program manager we interviewed, this clause is a powerful motivator for researchers. When asked how often the contracts are terminated, we were told that it happens “more often than you think.”

Once awarded, the projects are very closely monitored by DARPA managers. They meet with the teams weekly by phone and monthly in person, and conduct frequent site visits. According to our respondent, project managers are involved closely enough to justify their authorship on the resulting publications. The DARPA project manager that we spoke with also plays a role in facilitating research, by helping with IRB and FDA approvals and by securing additional money for manufacturing. DARPA staff understands and accepts that the contract termination clause and extremely close involvement of DARPA during project execution are unacceptable to some scientists.

**VA Innovation Initiative (VAi2).** In addition to speaking with other federal agencies about their processes for developing and managing research portfolios, we examined an internal VA program that uses different funding mechanisms to find solutions to problems affecting Veterans. With a budget of $102.5 million, VAi2 engages various communities through industry and employee competitions, prize contests, and special programs. In industry competitions, all types of organizations (small, large, non-profit, for-profit) are invited to submit concept papers to address a challenge identified by VA. Following review by VA and non-VA experts, a small subset of applicants are invited to submit full proposals, of which an even smaller number are selected for funding. VAi2 staff works with winning teams to finalize their proposals. So far, VAi2 has held two rounds of industry competitions, in 2010 and 2011. Almost 600 ideas were submitted and 37 projects funded. VAi2 also taps into the VA workforce by sponsoring employee innovation competitions. Interested employees can submit ideas for several topics advertised by VAi2 and participants vote on each other’s submissions. Through this “crowdsourcing” approach, VAi2 received 15,000 ideas and funded 72 in the past two years.

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294 [http://www.va.gov/vai2/Programs_Home.asp](http://www.va.gov/vai2/Programs_Home.asp)
Because the program is new, the process for identifying challenges has not yet been completely worked out. In 2010, the first program year, challenges were suggested by VISNs and VBA and six focus areas were selected based on this input. In 2011 VAi2 invited the Deputy Secretary and representatives from all major units at VA (approximately 30 people) to a planning roundtable. All participants were asked to prepare presentations on issues which they thought should be addressed. This resulted in 15 viable ideas, of which 5 made the final cut.

VAi2 closely monitors the projects. Each innovation is assigned an innovation coordinator, who is responsible for project oversight. At the end of the project awardees submit a report, which is reviewed by the coordinator. In addition, VAi2 staff not directly involved with individual projects periodically assesses the whole portfolio.

**Limitations of the approach**

Before making recommendation to VA, we believe that it is important to point out the limitations of our analyses. These limitations fall into three groups. First, we relied on the survey of PIs as a major source of outcome data. The survey response rate was 54% and we made an assumption that the data available to us are representative of the larger population. This assumption is supported by bias analysis, which showed that respondents and non-respondents were similar on Service affiliation and degree, the two variables which could be compared. In addition, survey data are a snapshot in time and reflect the achievements and the composition of the research community as they were at the time of the survey. However, the VA research community appears to be reasonably stable, with 61% of respondents having been there for at least 11 years and 84% for at least 6 years (data not shown). Finally, outcomes data were self-reported and more subjective impacts (such as improvements in quality of life) may have been exaggerated by survey respondents. We assume that factual impacts, for example whether research resulted in clinical trial, are fairly accurate.

Second, the underlying logic of the study assumes that the outcome measures that are available to us serve as a reasonable proxy for the program goals we would like to measure. However, this relationship is not totally provable – for example, an increase in publications does not necessarily correspond to a proportional increase in knowledge discovery. Furthermore, our strategic recommendations are based on the assumption that investment in research will not only have direct impacts on health care outcomes, but that it will reduce these expenditures over time. Both of these assumptions may not be accurate. In fact, advancements in research may increase the cost of care, rather than reduce it.

Third, VA should be mindful that ICD-9 and demographic projections are assumptions based on past trends and may not be accurate. Other factors may significantly influence future trends, such as future military conflicts or the economic situation in the US. For example, the use of chemical weapons would completely change the nature of war injuries; significant growth or decline in the job market might change the composition and size of the enrolled Veteran population. In addition, VA tends to underutilize ICD-9 codes because these codes are not used to bill insurers. Therefore, expenditure data are likely to be underestimated. Furthermore, some ICD-9 data are suspect. We noticed significant variation in the number of patients from year to year and obvious mistakes in coding (such as some pregnancy conditions being coded as prevalent in males). In addition, we could not assign approximately 20% of PIs to one of the 12 diseases because these PIs either do not work on diseases or do not have a publication footprint, which we required. This represents a sizable portion of VA research investment. It is also important to keep in mind that we classified complex research topics into 12 simple categories. Finally, as we did not have data on research expenditures per PI, we used number of projects as a proxy measure for research costs.
Conclusions and recommendations

Our analyses of the VA research portfolio showed that it is currently well aligned with health care costs and patient volume, the measures that we used as proxies for Veterans’ needs. Using demographic trends and historical ICD-9 data, we attempted to make predictions of future Veterans’ needs. Our analyses, summarized in Exhibit 85, showed that:

- In the past two years, disease categories with the highest total expenditures and most patients included circulatory system, musculoskeletal system, nervous system, and mental disorder.

- While clinical enrollment trends are projected to decrease over the next 20 years, the percent of elderly and women Veterans is expected to increase. Disease categories with a high percentage of the elderly included cancer, circulatory system, and nervous system.

- The disease categories with more than 100,000 elderly patients included circulatory system, nervous system, and endocrine system.

- The disease category with the highest percentage of women (excluding women-specific diseases) was infectious disease.

- The disease categories with the highest costs include musculoskeletal, circulatory, mental, and genitourinary systems (PTSD is included in mental disorders).

- The top three diseases with the highest increase in cost per patient included complications of pregnancy (350% increase), heart valve disease (94% increase), and inflammatory disease (78% increase).

- Several diseases in musculoskeletal, circulatory, endocrine, and nervous system and mental health groupings have increased by more than 50% in costs or number of patients from 2005 to 2011. The top two conditions with an increase in the number of patients included organic sleep disorders (367% increase) and nutritional deficiency (101% increase).

- Unemployment and homelessness have significantly increased since 2005.
Based on the analyses described in this report we make several suggestions.

- For future positioning of the VA research program ORD should consider supporting those research areas which now afflict or are expected to afflict many Veterans and are likely to overtax the health care system. These include diseases of the musculoskeletal, circulatory, and nervous systems (Exhibit 17). Note, however, that the ORD research portfolio is already weighted toward the nervous and circulatory systems (11.5%, and 10.7% of research projects, respectively, Exhibit 5). Homelessness and unemployment are also growing among Veterans, so ORD may consider directing additional research support to projects or programs that look for solutions to these problems (e.g. what types of training would be most effective to enable Veterans to re-enter the workforce).

- VA might benefit from testing the type of strategic planning approach used by NIBIB, which we saw as the most applicable to ORD, because of the similar funding process and shared focus on biomedical research. At NIBIB, the set of priority areas is generated by the senior leadership, discussed with other stakeholders, vetted by the Advisory Council, and communicated to the research community. The final strategic plan is based on the synthesis of this input. We believe that this approach would offer ORD several advantages. First, it could help ORD identify new research directions. Furthermore, by engaging in this process, ORD will make its priority setting activities more transparent to VA/VHA leadership, its research community, Congress, and VSOs.
For particularly challenging problems or for problems with no expertise within VA we suggest reaching out to the extramural academic community and to industry (we understand that there might be legal barriers to doing that). For example, diseases of pregnancy have shown dramatic increase in both cost and patient volume over the past several years. We assume that VA currently has little expertise in this area. If VA wishes to increase support for women’s health issues, DARPA-style or VAi2-style funding approaches could be explored, although to the best of our knowledge the efficacy of these mechanisms has not been evaluated. Regardless of whether the problem is solved, engaging outside communities will increase VA research program visibility.

Finally, we recommend establishing a cross-Service data collection system to facilitate program planning and oversight. In our study, we had to rely on a costly large-scale survey, Web of Science, and the NIH database to piece together the information, and yet, as discussed in the limitations section, the data are not fully reliable. Ideally, the system should annually or bi-annually collect data from all PIs on their research focus, funding from all sources, publications, patents, FDA submissions, clinical trials, devices, therapies, and other research outputs of the type captured in this study. Because PIs are already overburdened with paperwork, the system should be set up to be as automated as possible, so that information from other sources can be pre-loaded. We are aware that ORD is already in the process on putting together a research management system along these lines. When in place, such a system would become a useful tool for monitoring program performance, reporting results, justifying funding choices to stakeholders, and crafting future program directions.
Chapter 8: Study Conclusions and Recommendations

The goal of this study was to assess the effectiveness of the VA medical research program in fulfilling its mission of creating knowledge, developing researchers, and improving health care of Veterans and the nation. Our data collection activities included interviews with 65 individuals within and outside of VA, a survey of ORD-funded researchers and ACOS, and review of numerous documents and datasets.

We concluded that ORD-funded investigators are well-regarded and productive members of the scientific community. Most surveyed researchers have faculty positions at major research universities, including UCLA, University of Washington, UCSF, Stanford, University of Michigan, Yale, and many others. More than 60% have titles of professor or associate professors. The researchers serve on journal editorial boards (24% of survey respondents), peer review panels (52% of survey respondents), and federal advisory councils (10% of survey respondents), and play leadership roles in professional societies (12% of survey respondents). Further, in the exceptionally competitive funding climate, VA researchers were able to obtain over $700 million in extramural support per year. Finally, a search of the publication database Web of Science for 2010 yielded more than 10,000 articles which had a VA address for at least one of the authors; ORD-funded PIs published 1.5 papers/year, on average, in journals with high impact factors. This publication rate per PI is comparable to NIH-funded investigators.

In addition to discovering knowledge, the mission of the program is to improve health care of Veterans. We asked survey respondents to indicate whether their research resulted in various clinical and quality of life outcomes. While these data were self-reported and as such could have been exaggerated, the VA research appears to have had important consequences. Specifically, 650 researchers responding to the survey\(^{295}\) reported that their work resulted in:

- Clinical trial, 53%
- Use of new drug, regimen, or treatment, 31%
- Better patient and provider education, 48% and 55%
- Improvements in patient life expectancy and quality of life, 16% and 60%
- New devices to help disabled Veterans, 8%
- Reduction in health care costs, 33%.

Finally, in 2010 ORD received 10 patents and 169 licenses and filed 31 patent applications. The search of the federal clinical trials database (clinicaltrials.gov) indicated that 28 Phase IV clinical trials were conducted by VA, of which 11 were marked as completed.

One of the reasons for establishing the research program at VA in the 1920s was to attract academic clinicians to the VA system and we examined program effectiveness in this area. Our study revealed that the research program is an important recruitment tool: in the survey, 87% of respondents believed that the program was important or very important to the recruitment and retention of talented clinicians to VA. In addition, 78% and 92% of researchers said that research was a factor in their decision to come to and to remain at VA.

Contemporary biomedical research is a complex enterprise requiring extensive supporting infrastructure and we investigated whether the research community has what it needs to carry out research projects.

\(^{295}\) BLRD researchers were not asked to report information on clinical and quality of life outcomes.
We found that IT support, credentialing, purchasing, hiring, and human subjects protection processes were viewed by the research community as slow, inefficient, and even inhibitory to research progress. For example,

- 51% of researchers disagreed or strongly disagreed with the statement “OI&T supports your research program”
- 37% of researchers disagreed or strongly disagreed with the statement “VA credentialing requirements are appropriate”
- 70% of dissatisfied of strongly dissatisfied with HR policies for hiring research staff.

IT support, in particular, emerged as highly unsatisfactory. In addition to delays in service, the community reported lack of customer orientation and understanding of research process and needs; difficulties in data access and sharing; and mismatch between data sensitivity and security. In comparing the survey of the same community conducted in 2000 with our survey we found that the level of satisfaction with IT services fell from 46% to 20%. These problems are very serious, as sharing of data with the research community is instrumental to scientific success. Further, the integration of research and health care systems at VA offers unique and important opportunities to study quality and effectiveness of care and restrictive IT policies make these data inaccessible.

Another serious shortcoming that the study revealed is the heavy burden of regulatory requirements on the research community. The survey respondents indicated that they spend 10% of their time on compliance-related activities. This number is particularly striking when compared to the time allocated to other activities, including 38% on research and 18% on clinical care. We found that ACOS – who are meant to serve as mentors to the researchers in their facility and to direct and supervise the research program – reported devoting numerous hours to preparing for and hosting oversight and auditing visits from ORO, OIG, OSHA, AAOHRPP, and other entities. In the survey, 86 ACOS reported 469 compliance visits in 2010 alone, requiring nearly 100,000 hours of ACOS’ and their staffs’ time.

This level of regulatory oversight is taking its toll on the research community: 60% of ORD-funded PIs and 83% of ACOS believed that excessive regulatory burden is a factor impeding recruitment to VA. Finally, we estimate that the cost of complying with the requirements for the entire research community might be as high as $100 million per year. Note that significant regulatory burden is not unique to VA. However, interviewees familiar with other organizations suggested that VA policies were excessive even in today’s increasingly regulated environment.

After our findings were reported to VA, OPP and ORD each selected a problem for further study in the second phase of the project. The first problem was to identify sources of regulatory burden and identify potential solutions to its reduction. Based on the interviews and document analysis we concluded that for all three regulatory areas examined – human subjects protections, sensitive data access, and training – VA requirements significantly exceeded what was minimally necessary. We suggest that VA should carefully examine its regulatory requirements and bring them in line with the national standards.

The second problem was to explore alternative funding allocation strategies that ORD should consider to best meet Veterans’ needs. We found that at present ORD research maps well onto the diseases and conditions for which Veterans seek care. Using demographic projections, we established that the number of elderly and women Veterans is expected to significantly increase in the next 20 years. Thus, ORD might consider continuing or increasing its investments in the research that could lead to improved understanding/treatments of conditions prevalent or growing in these groups. We also concluded that funding allocation and strategic planning processes at ORD lack transparency and inclusiveness. Finally, ORD currently does not have an integrated, cross-Service system to collect research outcome data,
facilitate project management, and reduce the amount of research-related paperwork. In summary, our recommendations are as follows.

- **Improve IT support.** We believe that better understanding by IT staff of research data, processes, and needs, as well as greater awareness in the research community of OI&T constraints and the protections those constraints provide, would go a long way to resolving existing problems. To bridge the apparent gap between OI&T and the researchers, we recommend creating an ORD/OI&T liaison position.

- **Re-evaluate and clarify policies and procedures for data access, sharing, and dissemination.** While the OI&T leadership appears to realize that manuscripts, de-identified clinical data, and several other research data types are not sensitive, they are treated as such in the field. Thus, non-sensitive data should be clearly identified to the information security officers and exempt from undue protections.

- **Make training requirements more targeted and less frequent.** We recommend that VA review all training courses currently required for the research community and determine which courses can be eliminated or be taken less frequently. In addition, a better system should be developed to identify who needs a given course for their current duties at VA and whether these individuals already know the content of the course. Finally, VA and its affiliates should work together to develop an approach to eliminate duplicative training requirements.

- **Bring the human subjects protection program in line with national standards.** We recommend eliminating or simplifying all the requirements exceeding the Common Rule. This would include transferring decision-making authority related to research protocols to IRBs, simplifying consent forms, and removing various extraneous administrative and oversight procedures.

- **Improve the transparency and inclusiveness of the strategic planning process.** To the best of our knowledge, many funding allocation decisions are made by a small group of senior leaders at the Central Office. While this approach is certainly used by other R&D funders, we believe that ORD might benefit from testing the type of strategic planning process in place at the National Institute of Biomedical Imaging and Bioengineering (NIBIB) as well as other NIH institutes. At NIBIB, the set of priority areas is generated by the senior leadership, discussed with other stakeholders, vetted by the Advisory Council, and communicated to the research community. The final strategic plan is based on the synthesis of this input.

- **Establish a research outcome data collection and grant management system.** Our study required extensive and costly data collection efforts, and yet was limited by the type of data that were available. We suggest that ORD should put in place a cross-Service data collection system to facilitate program planning and oversight. Ideally, the system should annually or bi-annually collect data from all PIs on their research focus, funding from all sources, publications, patents, FDA submissions, clinical trials, devices, therapies, and other research outputs of the type captured in this study. Because PIs are already overburdened with paperwork, the system should be set up to be as automated as possible and to be able to draw data from other sources. Ideally, the system should also keep track of the type of research performed by each PI, so that only the appropriate regulatory requirements are quickly triggered. We are aware that ORD is already in the process on putting together a Portfolio Categorization and Reporting Tool as well as a Research Administration Management System (RAMS) along these lines.
• **Continue to support and possibly increase funding for research areas which already afflict or are expected to afflict many Veterans.** These include diseases of musculoskeletal, circulatory, and nervous systems (prevalent in elderly) and infectious diseases and conditions of pregnancy and childbirth (prevalent in women). ORD should also continue to support research to mitigate homelessness and unemployment, which we found to be on the rise.

We believe that addressing these weaknesses will dramatically enhance the satisfaction of the research community and improve program effectiveness and impact.
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