DEPARTMENT OF VETERANS AFFAIRS



Congressionally Mandated Report: Nonprofit Research and Education Corporations

December 2022

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I. Background

The Veterans Benefits and Services Act of 1988 (P.L.100-322 as amended; 38 U.S.C. § 7361-66) permits the Department of Veterans Affairs (VA) to authorize the establishment of Nonprofit Research and Education Corporations (NPC) at VA medical centers (VAMC). This laid the foundation for the creation of unique partnerships to conduct VA-approved research and education. P.L. 100-322 allows the establishment of private, state-chartered, nonprofit entities to provide flexible funding mechanisms for the administration of funds, other than those appropriated to VA, for the conduct of VA-approved research.

II. NPC Role in Support of VA Research and Education

The foundation for the creation of unique partnerships to conduct VA-approved research and education is laid out in 38 U.S.C. § 7361-66. This authority allows the establishment of private, state-chartered, nonprofit entities to provide flexible funding mechanisms for the administration of funds, other than those appropriated to VA, for the conduct of VA-approved research and education.

III. NPC Locations

VAMCs throughout the country have long recognized the benefit of establishing NPCs to help support the conduct of VA-approved research and education activities. In 2021, there were 79 NPCs located in 43 states, Puerto Rico and the District of Columbia. All of the NPCs filed annual reports. There were 73 research and education NPCs and 6 research-only NPCs. As shown in Table 1 below, NPCs vary greatly in size. Revenue indicates the funds received by the NPC:

Table 1: NPCs by Revenue

Revenues Range	# of NPCs (2021)	# of NPCs (2020)	# of NPCs (2019)	# of NPCs (2018)	# of NPCs (2017)	# of NPCs (2016)
Below \$500K	19 (24%)	20 (25%)	19 (23%)	22 (27%)	27 (33%)	22 (27%)
\$500K- \$1M	9 (11%)	15 (19%)	14 (17%)	13 (16%)	12 (14%)	19 (23%)
\$1M- \$ 10M	44 (56%)	39 (49%)	42 (53%)	41 (50%)	38 (46%)	36 (43%)
\$10M & Above	7 (9%)	6 (7%)	6 (7%)	6 (7%)	6 (7%)	6 (7%)
Total NPCs	79	80	82	83	83	83

IV. Annual Reporting

Under 38 U.S.C.§ 7361-66, NPCs must submit a detailed report of their operations, activities and accomplishments during the previous year to VA. The Veterans Health Administration (VHA) Handbook 1200.17, VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C., Sections 7361 through 7366, dated April 27, 2016, requires each NPC to submit an annual report to VA's Chief Research and Development Officer on or before June 1 of each year. VA's Nonprofit Program Office (NPPO), located in the VHA Office of Research and Development (ORD), reviews the NPC annual reports and is responsible for summarizing the information for the NPC annual report to Congress. The information submitted by NPCs consists of, but is not limited to, IRS Form 990 – Return of Organizations Exempt from Income Tax, audited

financial statements, auditor's management letter (if applicable) and related revenue and expense information.

V. Financial Reporting

Revenues

In June 2022, NPCs reported \$313,077,791 total revenues during the 2021 reporting period, including interest income and other miscellaneous receipts. This was a record high for NPC revenues and represents a 12% increase in NPC revenues from the record amount recorded the prior year. From 2000 through 2007, total NPC revenue trended up. In 2008 and 2009, revenues decreased. Revenues increased substantially in 2010 and 2011, were flat for 2012, but increased again in 2013, 2014 and 2015. Revenues for 2016 decreased by 1.7% and again decreased by 2.8% for 2017. Revenues rebounded strongly in 2018, increasing by 5.3% and again increasing by another 3.8% to the record high achieved in 2019 with a small decrease of 1.2% in 2020. Figure 1 below illustrates these changes. Fifty-six NPCs reported an increase in overall revenues in 2021 compared to 36 in 2020. For 2021, 23 NPCs experienced declines in revenues.

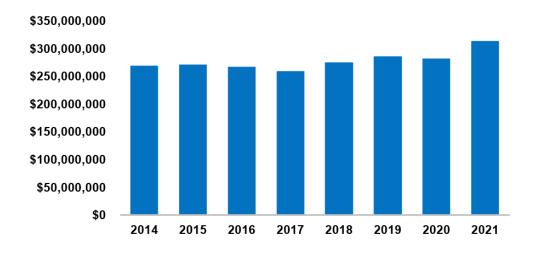


Figure 1. NPC Annual Revenues - 2014 to 2021

Under the title 38 statutory reporting requirements, NPCs are required to report research and education revenues and expenditures separately. In addition, they must report revenues based on Governmental or non-governmental (private) funding sources. About 98% of the total revenue was received in support of research, while less than 1% was received in support of education (see Figure 2 on page 3). The remaining 1% was received from other sources such as interest income.

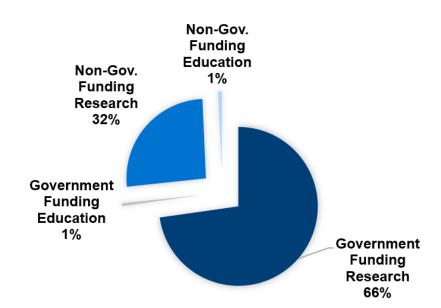


Figure 2. 2021 NPC Revenues by Funding Source

As in the previous year, revenue from Governmental research and education sources comprised the largest component of funding received by NPCs (approximately 73%). In 2021, Governmental funding increased by 14% to \$228 million, from the previous \$197 million in 2020.

Revenues from non-governmental sources increased 2%, from \$81 million in 2020 to \$83 million in 2021. Other revenue sources (e.g., interest income) decreased by approximately \$1 million to a total of \$1.9 million.

In 2021, the number of NPCs reporting revenue from Governmental sources (including VA) was 71, an increase of 4 from 2020. This was due to the Small Business Administration's funding of the Payroll Protection Plan.

Funding Sources

NPCs continue to obtain funding from diverse sources, including the private sector, charitable foundations, private individuals, state and local governments, universities and Federal entities such as the National Institutes of Health (NIH), Department of Defense (DoD), and Centers for Disease Control and Prevention.

VA appropriated dollars that are being directed to NPCs are for costs associated with the Intergovernmental Personnel Act (IPA) (5 CFR part 334) assignment agreement reimbursements or are funds from another agency or private entity that have been passed through VA to NPCs.

NPCs are required to identify the funding sources for both Governmental and non-governmental amounts greater than \$25,000 (see Figure 3 below for the breakdown). For 2021, the total revenue received from these sources was \$219 million.

2021 Revenues

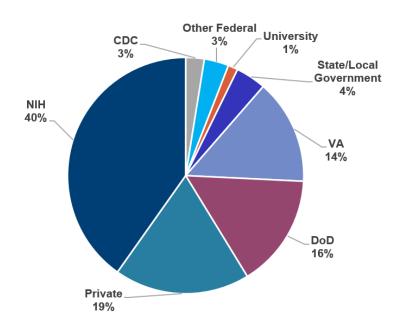


Figure 3. >\$25,000 by Funding Source

Expenses

In June 2021, NPCs reported expenses totaling \$294,224,902, an increase from 2020 expenses which were \$282 million. These expenses financed research projects and their supporting infrastructure as well as salaries, equipment and other research and education-related costs. NPCs employed approximately 2,500 people, supported more than 2,100 principal investigators and administered approximately 3,700 research projects.

Because the statutory purpose of NPCs is to facilitate VA research and education, all funds spent must support those activities except for amounts that cover NPC administration. Figure 4 on page 5 highlights the expenses over the past 8 years. The expenses increase as the revenue increases.

\$300,000,000 \$290,000,000 \$280,000,000 \$270,000,000 \$260,000,000 \$250,000,000 \$240,000,000 2015 2016 2017 2018 2019 2020 2021

Figure 4. NPC Annual Expenses, 2015-2021

During 2021, approximately 54% of the total expenses covered salaries and benefits; less than 1% of the total expenses covered travel; and the remaining 45% represented other expenses in direct support of VA research and education activities or NPC business operations.

NPCs continue to spend a relatively small amount on administrative expenses which averages about 17% (\$49 million) of the total expenditures for 2021. Figure 5 below notes the average administration costs for NPCs. This has remained steady for many years increasing by 1% at a time.

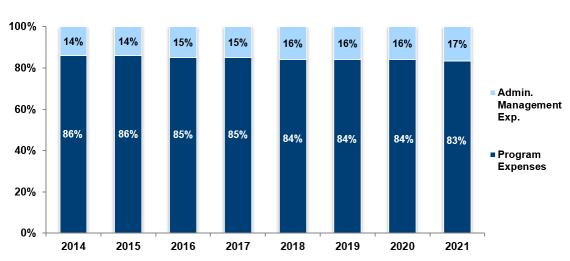


Figure 5. NPC Total Combined Administrative Management Expenses vs. Direct Program Expenses, 2013-2021

Compensation Expense

During 2021, 79 NPCs reported compensation expenses including benefits totaling \$160 million, a 5% increase from 2020. The NPC salary expenditures supported a variety of personnel (including research technicians, pharmacists, scientists, nurses, physicians and administrative staff).

Of the \$160 million spent for compensation, 77% (\$124 million) was used to support personnel directly engaged in VA research. Approximately 22% (\$35 million) was expended for NPC administrative salaries and benefits. Slightly more than \$1 million or less than 1% was expended in support of staff involved in educational activities. Figure 6 below highlights the compensation paid to NPC personnel.

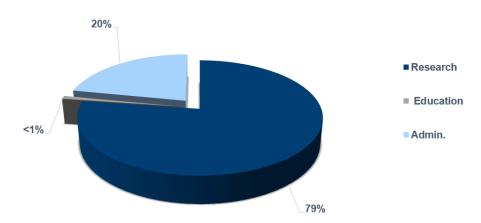


Figure 6. NPC 2021 Compensation Expenses by Category

Travel Expenses

NPCs support travel for VA and NPC personnel to attend scientific and educational meetings, seminars and conferences. VA benefits from such travel because it enhances the ability of VA staff to pursue research and education endeavors important to VA's health care, training and research missions. Forty-six NPCs reported travel expenditures totaling \$386,122 for 2021, which was down sharply from the prior year by \$1.3 million or 68%. Figure 7 on page shows the total travel expenses over the last 8 years.

Of the \$386,122 in travel expenditures, approximately 78% supported travel for personnel directly engaged in research or education activities.

\$4,500,000 \$4,000,000 \$3,500,000 \$3,000,000 \$2,500,000 \$2,000,000 \$1,500,000 \$1,000,000 \$500,000 \$0 Travel Expense **2014** \$4,305,415 **2015** \$4,065,220 2016 \$4,180,356 2017 \$4,399,880 **2018** \$4,334,368 **2019** \$4,393,835 **2020** \$1,268,600 **2021** \$386,122

Figure 7. NPC 2014-2021 Total Travel Expenses

Other Expenditures

While furthering VA's research and education missions, NPCs incur other costs in addition to payroll, benefits and travel. During the 2021 reporting period, other expenses totaled \$134 million, up by 5% from \$128 million in 2020. They included, but were not limited to, insurance, accounting, auditing, consulting services (statisticians, information technology experts, etc.), legal fees, supplies, postage, shipping, equipment purchases, rentals and maintenance, printing, publications, utilities and conference registrations.

Payees

Each NPC hires employees and contracts with various vendors ("payees") to support the conduct of VA-approved research and education activities.

The vendors provide products and services that sustain research, education and business operations. Any payee receiving more than \$50,000 per year is identified in the NPC report and is presented in Figure 8 found on page 8.:

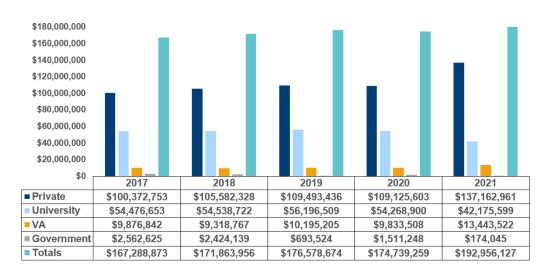


Figure 8. Chart of NPC Payees Greater than \$50K by Type, 2017-2021

Figure 8 above lists the four major types of payees and provides the total amount paid to each type. Private payees include employees, consultants, etc., that receive over \$50,000 in one fiscal year. State and private university payees may include reimbursements from grants or sub-awards. VA reimbursements are costs reimbursed in support of VA research and education activities. Other Governmental payees include sub-awards or pass-through funds to non-VA Government entities.

Financial Position

NPCs reported a net worth totaling \$231,522,734 at the end of 2021, an 8% increase from 2020. Gross assets under management were \$364 million and liabilities were \$133 million. It should be noted that in many cases the NPCs include funds that are obligated for the future performance of research projects in net worth. Although this is acceptable under the U.S. generally accepted accounting principles, there is nonetheless an obligation to expend project funds counted as equity in order to accomplish research and education projects. Unencumbered net worth for all the NPCs combined is estimated at \$63 million, up by 8.5% from the prior year.

The ratio of net worth to revenues was 74% for all the NPCs. For the top 20 NPCs by revenues that comprised 54% of total revenues, the net worth ratio was 41%. Some large NPCs that rely heavily upon awards from NIH, DoD and other Federal agencies, had substantially lower net worth ratios than the average and have been advised to conserve their net worth as best they can and to augment it when possible.

VI. Projects, Activities and Accomplishments

VA researchers conducted a variety of projects during the 2021 reporting period. The NPCs facilitated these projects. Many of these research projects were clinical trials studies that focused on the treatment of medical conditions prevalent in the Veteran population. Veterans benefit from getting access to innovative cutting-edge

pharmaceuticals and medical devices. Many Veterans who participate in VA clinical trials studies benefit from the actual "hands on" care provided, but also directly from the interaction between VA, NPC staff and other participants.

In support of VA's research programs, in September 2012, the VA Office of General Counsel established the Specialty Team Advising Research (STAR). This is a new team consisting of a small group of VA attorneys who address the needs of the VA enterprise including the NPCs in their role of supporting VA's approved research and education programs. STAR advises on many topics including the review and approval of various research agreements such as cooperative research and development agreements, nondisclosure agreements, subawards and various partnerships. Having this small but highly capable team of legal specialists has greatly helped VA's research programs and NPCs' growth.

The quality of care given to Veterans enrolled in clinical studies is exceptional and is a direct result of the close one-on-one relationships between the caregivers conducting research and the Veterans. VAMCs may potentially benefit from drugs and devices donated by sponsoring institutions and pharmaceutical companies, as well as from NPC salary support for nurses and physicians caring for Veteran patients enrolled in clinical studies.

NPCs also support VA in many ways beyond administering funds. Several examples are listed below:

- Renovate and upgrade VA research infrastructure;
- Provide funds, staffing and training support to VA and affiliate universities to help cover Institutional Review Board requirements;
- Pay for expenses related to recruitment of research investigators to the VA system;
- Fund seed grants to new investigators to aid them in establishing their VA research careers;
- Employ support staff for VA research projects;
- Cover the cost of training VA research personnel in topics such as research compliance, good clinical practice and board governance;
- Underwrite bridge funding for VA investigators who are between research grant awards:
- Support travel and registration fees for VA investigators to attend scientific conferences:
- Procure personnel, equipment and supplies for VA animal research facilities;
- Provide funds for research pharmacy staff and equipment; and
- Host national educational conferences for VA personnel with incidental attendance by health professionals from surrounding communities.

VII. Conflicts of Interest

NPC directors, officers and employees are subject to the conflict-of-interest policy adopted by that NPC. VA employees who serve as NPC directors as part of their official VA duties are also subject to the Federal conflict of interest laws and regulations. If at any time there is a conflict with the NPC policy, the Federal conflict of interest laws and regulations take precedence.

VIII. VA NONPROFIT PROGRAM OVERSIGHT BOARD

In 2004, VA senior leadership created the VA Nonprofit Program Oversight Board ("Board") to serve as VA's senior management oversight body over NPC activities and programs. The Board meets on a quarterly basis to review the activities of NPCs for consistency with VA policy and interests. The Board may also make recommendations to the Secretary and Under Secretary for Health concerning changes to, and the implementation of, VA policy regarding NPCs. Board membership is limited to VA employees and includes the following:

- Under Secretary for Health, or designee;
- General Counsel:
- Assistant Deputy Under Secretary for Health for Operations and Management;
- Chief Research and Development Officer;
- Chief Academic Affiliations Officer:
- Chief Financial Officer for VHA, or designee;
- Member, Office of Research and Development Field Research Advisory Committee;
- Field Associate Chief of Staff -Research, VAMC; and
- Field Designated Education Officer, VAMC.

IX. Independent Audit Reports

VA NPPO reviews the independent audit reports and related NPC audited financial statements for NPCs. NPPO also reviews other documents such as the independent audit management letters, lists of program activities and accomplishments and supplemental revenue and expenditure information. This oversight is performed to obtain substantive evidence of accountability and to have a balanced picture of NPC program activity.

Any material weaknesses or significant deficiencies in internal controls and related recommendations made by NPCs' independent auditors are noted. NPPO tracks these from year to year to determine whether NPCs have taken the appropriate corrective actions as recommended by their independent audits. Under title 38 U.S.C. § 7366(b) each NPC with annual revenues more than \$500,000 for the year is required to obtain an independent external audit of its financial statements for the year. NPCs with annual revenues between \$100,000 and \$500,000 must obtain independent external audits every 3 years. For those NPCs with \$100,000 or less in annual revenues, an

independent external audit is not required. For fiscal year (FY) 2021, 12 NPCs were not required to obtain an independent audit. Of the 79 NPCs, 67 (or 85%) submitted audited financial statements. For 2021, 99% of the total NPC revenues and 99% of total expenses were subject to independent external audits.

There are three ascending levels of independent audits, and they are as follows:

- (1) Generally Accepted Auditing Standards (GAAS) in the United States of America Audit: This audit requires the auditor to plan and perform the audit to obtain reasonable assurance that the financial statements are free of material misstatements. The auditor assesses internal controls, management and governance. An NPC receiving more than \$100,000 but less than \$500,000 in funding is required to obtain, at a minimum, an audit in accordance with GAAS once every 3 years.
- (2) <u>Generally Accepted Government Accounting Standards (GAGAS) Audit</u>: This audit obtains reasonable assurance that the financial statements are free of material misstatements. The GAGAS audit is used when required by provisions of laws, regulations, contracts and grants.
- (3) <u>Uniform Guidance or Single Audit</u>: This audit is performed in accordance with the Office of Management and Budget published rules and regulations, when annual expenditures are from Federal funds exceeding \$750,000. The uniform guidance audit is designed to provide assurance that the financial statements are reasonable and there is compliance with the legal and regulatory requirements of the Federal contract(s) and grant(s), and with sound internal controls.

Two NPCs were cited by their auditors for material weaknesses. Both had repeat material weaknesses from the prior year. NPCs with material weaknesses are working closely with NPPO and their external auditors to ensure correction of the weaknesses prior to the next audit.

NPPO requires an in-depth action plan from each NPC with material weaknesses, significant deficiencies and auditor recommendations. These audit action items are followed-up on by email and during periodic on-site reviews.

One of the two NPCs reporting material weaknesses were audited under the uniform guidance provisions. As noted above, NPPO will follow-up to ensure these material weaknesses and other deficiencies are corrected.

The Executive Director of each NPC is responsible for providing a copy of the auditor's report to the NPC's Board of Directors and involving the Board directly in the resolution of any deficiencies. NPPO has requested a remediation action plan from these NPCs.

X. NPPO OVERSIGHT PLAN AND RESULTS

NPPO is charged with conducting oversight for the 79 VA affiliated nonprofit research and education corporations nationwide. NPPO reviews the Operations Oversight Questionnaire with the Executive Director and the Internal Control Questionnaire that is provided in advance of the on-site visit. NPPO routinely tests samples of various transactions and accounting records, such as policies and procedures; cash disbursements; credit card purchases; bank statements and reconciliations; payrolls; and IPA assignment agreements.

The limited on-site reviews by NPPO are for the purpose of providing audit, investigative and oversight-related services that do not involve a GAGAS full financial, attestation or performance audit examination. NPPO's limited reviews are performance audits that emphasize compliance with VA policy and conformity to sound business practices and accepted internal control standards. NPPO's limited reviews are not designed to detect fraud, waste, abuse or other irregularities. NPPO's reviews are substantially narrower in scope than a financial audit examination. The objective of a financial audit examination is the expression of an opinion on the subject matter, and accordingly, no such opinions are expressed. (Government Auditing Standards 2011 Revision, Chapters 2.12 and 5.56, Pages 19 and 116). Nonetheless, NPPO reserves the right to extend its limited reviews; initiate other reviews or investigations; and arrange for complete GAGAS financial, attestation, or performance audits, if needed for effective VHA oversight. NPPO observes auditing standards set by the Comptroller General of the United States. These NPPO on0site reviews are conducted as described below:

- 1. All NPCs will be reviewed triennially regardless of financial condition. To accomplish this, one-third of the NPCs are audited each year.
- 2. More frequent or off-cycle on-site reviews may be scheduled at the discretion of the Nonprofit Program Oversight Board or the NPPO Director, as they are deemed necessary or desirable.
- 3. NPCs with identified operating problems or serious internal control weaknesses will be reviewed on-site annually or more often, if necessary, and monitored. Once the issues are resolved and the NPC receives a satisfactory review, its review schedule will generally be moved back to the triennial schedule.
- 4. New Executive Directors are welcomed and notified of the next Executive Director workshop and the availability of the NPPO website. They are also given NPPO staff contact information within the first 45 days of employment.
- NPCs that are starting-up, reactivating, merging or deactivating will be visited as needed.

- 6. NPCs with reported irregularities (e.g., by whistleblowers) will be reviewed onsite as soon as practicable and have appropriate follow-up action taken.
- 7. NPCs requesting on-site visits to resolve internal control, financial systems or financial management problems will be visited as soon as possible.

All 79 NPCs were reviewed by NPPO in the first three triennial periods, (i.e., FY 2011 through 2013, FY 2014 through 2016, and FY2017 through 2019). The fourth triennial period is longer due to Coronavirus Disease, 2019 travel restrictions. NPPO is pleased to report that there is a trend to much improved on-site review results in the last 3 years of audits conducted in FY 2017 through 2019. Wherever there are prior required actions, NPPO always follows-up on them in the subsequent review.

The on-site audits were necessarily postponed in March 2020 with the advent of the pandemic but were resumed again in late August 2021. The on-site audits were suspended in January and February of 2022. NPPO has worked for 14 years with a staff of three including the Director, Management Analyst and an Auditor. However, we are in the process of hiring one additional auditor.

Results for the three completed triennial review periods were as follows:

First triennial period, FY 2011–2013:

- 585 required actions
- 219 consultative suggestions
- 14 perfect reviews

Second triennial period, FY 2014 – 2016:

- 46 prior required actions
- 567 new required actions
- 92% success rate for implementing prior required actions
- 153 consultative suggestions
- 13 perfect reviews

Third triennial review period, FY 2017 – 2019:

- 27 prior required actions
- 270 new required actions (less than half of previous period)
- 95% success rate for implementing prior required actions
- 142 consultative suggestions

NPPO developed and implemented Executive Director and Financial Manager Training classes held in Kansas City late in the second triennial period. Largely as a result of these trainings, on-site review results greatly improved in the third triennial period.

Formal review reports are prepared for each NPPO on-site review and discussed with the NPC executive directors, the medical center directors and their key staff while on site. Additionally, the written responses from the NPCs to the review reports are incorporated into the reports before they are forwarded to the VHA Chief Financial Officer's office.

In addition to the routine triennial reviews, NPPO has performed non-routine whistleblower complaint, timekeeping and fraud investigations. NPPO has also performed several on-site management consulting engagements.

Other routine oversight conducted at NPPO offices include reviews of the following:

- 1. Annual reports due June 1 on forms prescribed by NPPO.
- 2. Annual audited financial statements due to NPPO by June 1.
- 3. Annual Form 990 income tax returns due to NPPO by June 1.
- 4. Remediation plans for all NPCs with material weaknesses reported by their independent auditors.
- 5. Remediation plans for all NPCs with significant deficiencies and auditor recommendations.
- 6. Monthly financial statements compared to budget and last year for NPCs with identified operating problems and/or inadequate reserves.
- 7. Immediate attention to all NPC requests for assistance or advice.

VA's Office of the Inspector General (VAOIG) has investigated five NPCs in the past 3 years. VAOIG has recently extended its investigation to two additional NPCs. As a result of these audits, VAOIG has made appropriate recommendations to VHA for oversight improvements. NPPO is leading the implementation of these VAOIG recommendations.

XI. NPPO Training

NPPO has been engaged in training the NPCs' Boards of Directors and other personnel by:

- 1) Providing training as part of the onboarding of new VA statutory members and NPC Executive Directors.
- 2) Providing a half-hour presentation on board governance during each on-site review.
- 3) Developing and facilitating a 2-day workshop for Executive Directors.
- 4) Developing and initiating a 2-day workshop for NPC top level financial managers.
- 5) Developing training courses designed for VA's Talent Management System for mandatory courses on:
 - a) Internal controls;
 - b) Conflict of interest.
- 6) Maintaining an easy-to-navigate, user friendly and informative website.
- 7) Developing PowerPoint trainings for the proper completion of Intergovernmental Personnel Act assignment agreements and for preparing for NPPO on-site reviews.

XII. Conclusion

VA-affiliated NPCs continue to make a substantial contribution to VA research and education missions. The 2021 NPC annual report to Congress demonstrates that NPCs are fulfilling their Congressional mandate in a responsible and conscientious manner.

Expertise in NPC governance and management is improving as evidenced in the onsite reviews and the NPCs' annual reporting to VA. VA-affiliated NPCs contribute significantly to the success of VA's research and education programs.

This report and NPPO's on-site reviews illustrate that NPCs are a highly efficient means to maximize the benefits to VA of externally funded research conducted in VA facilities. NPCs greatly facilitate research and education that benefit Veterans. Additionally, NPCs foster vibrant research environments at VAMCs, enhancing VA's ability to recruit and retain clinician-investigators and other talented personnel who apply their knowledge to state-of-the-art care for Veterans.

Department of Veterans Affairs December 2022