# **DEPARTMENT OF VETERANS AFFAIRS (VA)**

National Research Advisory Council (NRAC) Subcommittee



**Enhancing VA Research Relationships:** 

VA's Recommendations and Response to GAO

# Contents

Executive Summary	3
Enhancing VA Research Relationships: VA's Recommendations and Response to the GAO	5
Background	5
Process Overview	6
Determinations of the NRAC-SC	10
Successful Practices	11
Ensuring Understanding of the Overall Academic Partnership	11
Communication Mechanisms	12
Written Agreements	14
Critical Needs	16
Personnel Development	16
NPC Development as a Critical Partner	18
ORD Action Items	21
Conclusion	23
Appendix A: Decision Matrix for Handling of Extramural Awards	24
Appendix B: Works Cited	26

# **Executive Summary**

The Department of Veterans Affairs (VA) is committed to promoting and supporting VA Medical Center (VAMC) partnerships with Academic Affiliates (AAs). Effective affiliations are essential to the successful conduct of innovative research impacting health care for Veterans. To better understand these relationships, the House Committee on Veterans Affairs requested that the Government Accountability Office (GAO) review several aspects of the VA's research program. In July 2020, the GAO returned their findings in the report "Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and Academic Affiliates" (hereinafter referred to as the "GAO Report"). In this report, GAO found that VA medical centers (VAMCs) rely heavily on partnerships with AAs and VA nonprofit corporations (NPCs) for administering a significant portion of the funding that supports VA research (in the form of extramural grants and contracts). However, some VA facilities have difficulty communicating effectively with their AAs to support research relationships. GAO recommended the following: that the Veterans Health Administration (VHA) should 1) provide more information to its medical centers on "successful practices" for strengthening research relationships with AAs and 2) develop decision tools to help VAMCs determine whether NPCs or AAs should administer extramural grants.

The VHA Office of Research and Development's (ORD) Federal Advisory Committee, the National Research Advisory Council (NRAC), formed a subcommittee (NRAC-SC) to identify and recommend concrete actions that would address the GAO recommendations. The NRAC-SC began by reviewing the GAO report, existing reports, and summaries of prior national meetings and contracted reviews that addressed research partnerships. The GAO acknowledged that the interviewees for their project (stakeholders at NPCs, VAMCs, and AAs), while selected carefully to "represent variation in geographic location and funding," was a "nongeneralizable sample." Therefore, in order to develop a comprehensive data gathering approach to harvesting current successful practices while recognizing and addressing the challenges faced across the broad spectrum of unique VAMC-NPC-AA partnerships, the NRAC-SC conducted focus groups with a broad range of key stakeholders.

The NRAC-SC identified successful current practices and critical needs for enhancing research relationships among AAs, VAMCs, and NPCs from this all-encompassing approach. Successful practices were collected under three broad themes:

- Ensuring Understanding of the Overall Academic Partnership
- Communication Mechanisms
- Written Agreements

Similarly, critical needs were found to cluster in three broad categories:

- Personnel Development
- NPC Development as a Critical Partner
- Office of Research and Development Action Items

<sup>&</sup>lt;sup>a</sup> GAO, Veterans Affairs Research: Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and AAs, GAO-20-570, July. 17, 2020, Washington, D.C.

<sup>&</sup>lt;sup>b</sup> The "Westat Report" on VA extramural funding in September 2018, had interviewed more broadly across the VAMC and NPC community, but neglected to include the voice of the AAs in its report.

<sup>&</sup>lt;sup>c</sup> Stakeholders included: VA medical facility based Associate Chiefs of Staff for Research (ACOS-Rs) and Education (ACOS-Es), VA Nonprofit Executive Directors (EDs), VAMC and Veterans Integrated Service Network (VISN) leadership, and research leadership at AAs.

The NRAC-SC developed this document both to respond to the GAO's recommendations and as a useful guidance document for stakeholders. The NRAC-SC recommends a range of policies, practices, and procedures that have the potential to improve collaboration among the three key stakeholder groups (VAMCs, NPCs, and AAs). This report also addresses the challenges stakeholders face in administering extramural sponsored research. These recommendations capture, yet are not limited to, specific actions that can be tailored to each partnership according to the strengths and needs of the individual partners. Also provided is a link to an online toolkit of resources to support the key stakeholder groups.<sup>d</sup>

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<sup>&</sup>lt;sup>d</sup> The VA/Nonprofit Corporation/Affiliate Collaboration Toolkit is available for public use via the Office of Research and Development website at https://www.research.va.gov/resources/va-npc-affiliate-toolkit and is intended to be an evolving resource that expands its available range of sample documents and recommendations of successful practices through ongoing input from all stakeholder groups.

# Enhancing VA Research Relationships: VA's Recommendations and Response to the GAO

## **Background**

In recent years, several Congressional hearings have been held to investigate how extramural (non-VA appropriated) research grants were administered. Subsequently, the GAO was asked to review VA's extramural research policies and practices. The GAO examined the following broad questions: (1) how much money did VA receive from extramural funding sources, with a focus on the fiscal year 2019, and (2) how has VA supported VAMC's partnerships for extramural research, including the NPCs and AAs? The GAO's findings were published in a July 2020 report to the House Veterans Affairs Committee (HVAC): VA RESEARCH - Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and AAs. According to this report, VA received extramural research funding of approximately \$510 million in the fiscal year 2019 (FY2019), of which federal sources accounted for \$382 million (75 percent) and nonfederal sources accounted for the remainder (\$128 million or 25 percent). Extramural funding in FY2019 for VA research conducted at 92 facilities ranged from less than \$2 million to more than \$30 million.

To determine the current status of the VA's extramural research program at the field level, the GAO conducted a series of site visits to a "nongeneralizable selection of six VA medical centers and their associated NPCs and AAs," as well as interviews with: a) officials from VAMCs that work with either an NPC or AA but not both (2 sites); b) leadership from a VAMC that had only recently begun work with an NPC after a long-standing relationship with the AA (1 site); and c) leaders of small and medium-sized NPCs (4 sites). From their survey of these institutions, the GAO found that "some NPCs and AAs support VA research in additional ways" by providing things such as seed funding to new investigators; bridge funding to investigators with temporary gaps in research funding for their laboratories; consulting services to help investigators develop competitive research grant applications; additional information technology support beyond what the VA's Office of Information Technology (OIT) could provide; and core research facilities to allow access to shared equipment and technical services. This highlighted some of the important benefits of collaborative partnerships as recognized and encouraged by VHA's Central Office (VHACO).

The GAO recognized the VA's commitment to such partnerships as a key driver in advancing veterans' health, expanding veterans' access to clinical trials, and attracting and retaining top scientists and clinicians. It also recognized efforts of ORD to develop formal agreements with other national partners to help facilitate such collaborative research, including agreements with private foundations and other federal partners to enhance veteran participation in clinical trials. The GAO's report went on to delineate examples of success in partnership at certain sites where all partners (VAMC, NPC, AA) found mutual benefit in the tripartite relationship; other sites were identified where significant challenges existed for the VAMC and/or NPC to effectively engage with the AA and develop a strategic partnership, especially regarding the administration of indirect extramural funds used to support the research infrastructure. Ultimately the GAO recommended that:

1) The VA Under Secretary for Health should ensure its key offices, such as the Office of Academic Affiliations (OAA) and Office of Research and Development (ORD), provide VAMCs with examples of successful practices for strengthening research relationships with AAs and that such information reflects the lessons learned from VAMCs that have successfully cultivated these relationships, and 2) The VA Under Secretary for Health should ensure ORD, in consultation with the field, develops tools, such as a decision tree and successful practices, to help local VAMC officials decide which entity – NPCs or AAs – should administer extramural funding based on providing optimal support for research.

VA concurred with the recommendations and agreed to establish a working group with representation from VHACO (ORD and OAA) and the field (VAMCs and NPCs). This workgroup was ultimately formalized as a subcommittee (NRAC-SC) of the VA's National Research Advisory Council (NRAC). Membership of the NRAC-SC was comprised of representatives from ORD and OAA, VAMC Associate Chiefs of Staff for Research (ACOS-Rs), VAMC Associate Chiefs of Staff for Education (ACOS-Es), and Executive Directors (EDs) of NPCs. Ex Officio participants included designees from the Association of American Medical Colleges (AAMC), the National Association of Veterans' Research and Education Foundations (NAVREF), and the VA's Office of General Counsel Specialty Team Advising Research (OGC STAR). The group's composition offered rich perspectives from diverse subject-matter experts with years of practical experience in VA research, NPC administration, and academic affiliations.

To address the GAO's recommendations, the NRAC-SC set forth to execute the following:

- 1) Draft a document summarizing successful practices for developing and maintaining effective working relationships between VAMCs, NPCs, and AAs nationwide. The result is the document "Enhancing VA Research Relationships: VA's Recommendations and Response to GAO."
- 2) Launch an online toolkit of document samples and templates to assist medical centers in documenting and enhancing their research relationships. The toolkit will include examples of partnership agreements that delineate decision-making regarding administering extramural research funding when VA efforts and resources (e.g., equipment, personnel, patient specimens, or patient information) are used to conduct the research. The toolkit is not meant to be a final static product of the NRAC-SC but rather an ever-expanding resource that ORD would maintain for public use (https://www.research.va.gov/resources/va-npc-affiliate-toolkit). As new practices and written agreements are implemented in the field, and as ORD develops new guidance, the toolkit will offer an increasingly rich resource for developing successful relationships at individual sites according to the unique needs and strengths of the particular partners.

To accomplish these objectives, from October 2020 to October 2021, the NRAC-SC gathered information, data, and sample source documents to support its ultimate recommendations. A brief overview of the process utilized by the NRAC-SC follows.

#### **Process Overview**

1) <u>Initial Review of Historical Source Documents.</u> The NRAC-SC began its charge by reviewing the GAO Report as well as existing reports and summaries that addressed similar issues for research partnerships. The issues, challenges and recommendations identified in these source documents informed the nature of the questions that NRAC-SC used for the stakeholder focus groups to obtain a broader and more generalizable sampling. The stakeholder focus group process is described below, and the determinations of the NRAC subcommittee are presented in detail using supporting evidence from those focus groups. However, it is important to recognize that the themes identified in the source documents ultimately were echoed in the stakeholder focus groups, serving to underscore the generalizability of the conclusions drawn and recommendations made. The following list summarizes the source documents reviewed and their key takeaway messages:

- a) The September 2018 Study on Veterans Affairs (VA) Extramural Funding (<a href="https://www.research.va.gov/about/Study-VA-Extramural-Funding.pdf">https://www.research.va.gov/about/Study-VA-Extramural-Funding.pdf</a>) submitted by Westat to the ORD (hereinafter referred to as the "Westat Report"). This mixed-methods study incorporated statistical analyses of administrative data and thematic analyses of in-depth interviews, combining data from the Research and Development Information System database, 2014 2016 VA NPC Annual Reports, case studies of selected VAMCs, and in-depth interviews with 72 NPC Executive Directors and 74 ACOS-Rs. Notably, the Westat Report did NOT include interview results from leadership at AAs. The Westat Report's detailed findings were organized according to the questions asked of all interviewees and presented factually, but without ultimate conclusions or specific recommendations for action. The study's findings included, among other items:
  - i) A majority of respondents felt that NPCs were not used to their full potential, and indirect costs collected by the affiliate do not clearly benefit the VA.
  - ii) NPCs with written policies pertaining to grant administration tend to be larger and have higher revenue, on average, than those without written policies.
  - iii) The "preponderance rule" [a grant is administered at the institution where the majority of work occurs] is the most common approach to determining where awards are administered.
  - iv) A sizable share (42-45%, depending on the year examined) of AA-administered grants funded work conducted primarily or fully at VA.
  - v) At 1/3 of sites, the AA does not provide sub-awards to the NPC.
  - vi) Respondents identified potential VA benefits from affiliate services and resources such as laboratory space and equipment, access to core laboratories and animal facilities, computing and library resources, compliance infrastructure, and assistance with attracting, recruiting, retaining, and providing salary support for the best researchers.
  - vii) Respondents also reported various NPC benefits to further the VA research mission, such as rapid hiring of research support staff, providing travel funds for scientific meetings, sponsoring research events, providing pre-and post-award grant administration services, and increasing opportunities for veteran participation in clinical trials.
- b) A letter from the AAMC to the VHA's Chief Research and Development Officer (CRADO) offered feedback on the Westat Report and suggested follow-up by ORD, including additional interviews with the leadership of AAs to obtain their important perspectives.<sup>3</sup> The AAMC also presented some additional key recommendations:
  - i) The development of formal written documents can assist VAMCs, and their NPC and AA partners, in defining appropriate processes for administering extramural research.
  - ii) Increase consideration by AAs of subawards with the NPC for portions of extramural grants utilizing VA services and vice-versa.
  - iii) Enhance education of VA researchers to increase the visibility of NPCs and the services they offer.
  - iv) Increase communication among AAs, VAMCs, and NPCs, particularly to help reconcile potential dual appointed (VAMC, affiliate) investigator conflicts of interest.
  - v) Development of enhanced infrastructure at VAMCs and NPCs may better support extramural grants administration.

- c) NAVREF published its reaction to the Westat Report's findings (https://navref.org/news/12639646) and held an online seminar in November 2018 to field concerns and feedback from researchers.<sup>4</sup> This organization is a prominent advocate for effective NPC and VA-affiliated research. Key NAVREF recommendations included the need to understand the unique strengths and requirements of every NPC, VAMC and AA partner, and the need to develop collaborative communication mechanisms to support mutually beneficial processes. NAVREF recommended the following criteria as guidance for a decision algorithm:
  - i) Does the arrangement reflect local circumstances, including the strengths, weaknesses, and requirements of the entities?
  - ii) Does the arrangement avoid conflicts of interest (a non-conflicted individual should do the decision-making)?
  - iii) Is the arrangement the lowest cost alternative for VA and taxpayers?
  - iv) Is the arrangement logical, and does it meet explicitly stated criteria?
  - v) Is the arrangement mutually beneficial?
- d) A follow-up discussion of the Westat Report occurred in an ORD-convened meeting of ACOS/Rs and ACOS/Es on November 27, 2018. The group determined as an overarching principle that the question of who administers an extramural award should be based on which institution can provide the best support for the VA research to be conducted and accomplish the VA research mission. The summary report of the ACOS/Rs and ACOS/Es meeting recommended, among other things:
  - i) An assessment of practices promoting success at strong research VAs.
  - ii) A system to allow sharing of best practices to ACOS/Rs, ACOS/Es, and NPCs.
  - iii) A mentorship program to guide VA Research Programs and NPCs in the development of partnerships.
  - iv) A formal voice for the research programs in the Affiliation Partnership Council.
  - v) A meeting with ORD, NAVREF, AAMC, and field representatives of VA Research Programs, NPCs, and AA partners to discuss extramural research and how funding is administered.
- e) The April 2019 ORD- and NAVREF-sponsored meeting on Partnerships Aimed toward Collaborative Enterprise Research Solutions (PACERS) brought together the stakeholders identified during the November 2018 ACOS/R and ACOS/E meeting. NRAC-SC reviewed a draft summary of the presentations given and the discussions held (a final report was never issued). The document identified common challenges faced in establishing effective partnerships such as equitable administration of extramural grant awards, and pressures faced by dual appointed investigators when deciding which entity should administer their extramural grants. The document also presented some case studies of well-established and still developing tripartite partnerships among VAMC, NPC, and the AA.
- 2) NRAC-SC-led Stakeholder Focus Groups: To supplement the Westat Report and GAO Report data sources, the NRAC-SC conducted focus group interviews in March and April 2021 with four key stakeholder groups:
  - a) VA Medical Center Directors and VISN leadership
  - b) ACOS-Rs

- c) NPC EDs
- d) AA research leadership

At least two scheduled days and meeting times were presented to each stakeholder group to ensure that as many as possible could find a time to participate. Participants were informed that the discussions would focus on optimizing the collaborative relationships between VAMCs, VA NPCs, and AAs. Conversations were transcribed and later analyzed by the NRAC-SC. Each focus group responded to five questions:

- 1. What practices and processes at your site promote collaborative research opportunities between the AA, the VAMC, and the NPC?
- 2. What challenges currently exist in the relationships between your AA, VAMC, and NPC? What are potential solutions to these challenges?
- 3. What do you recommend for enhancing research collaborations between your AA, VAMC, and NPC?
- 4. Does your AA currently sub-contract with the NPC or vice versa? How effectively and smoothly does this work? Is it sufficient?
- 5. At the local level, should there be formal policies and agreements that specify the process for administration of extramural research grants by the AA and NPCs? How is this currently handled at your site?

Stakeholders unable to attend the focus group meetings could share their responses to the same questions via email. This representation provided unique, pertinent commentary from the broad stakeholders' perspectives, which the NRAC-SC considered in developing recommendations for this final report (detailed below under Determinations of the NRAC-SC).

- 3) A thorough review of existing VA policy documents provided an instrumental, contextual foundation for the NRAC-SC's recommendations. Policy documents reviewed included the following:
  - a) VHA Directive 1200.02: Research Business Operations Establishes standards and requirements for the proper and efficient operation of the VA facility's research service and offices regarding protocol submission, protocol review, formal communications, financial operations, and personnel.
  - b) Technical Amendment (September 6, 2017) to VHA Directive 1200.02: Research Business Operations Provides two revisions to the requirements for Memorandums of Understanding (MOUs) and other written agreement submissions and the language regarding the use of third-party spaces by VA.
  - c) VHA Handbook 1200.17: VA Nonprofit Research and Education Corporations Provides procedures and instructions governing VA-affiliated NPCs created under title 38 sections 7361 through 7366, United States Code (U.S.C.).
  - d) VHA Directive 1400.03: Educational Relationships Defines policies and procedures for the establishment, maintenance, and evaluation of medical, dental, nursing, and associated health professions educational programs in VA medical facilities. It also promotes the use of the Affiliation Partnership Council to discuss and oversee research relationships.
  - e) Affiliate Administration of Research Funds Memorandum Guides the Associate General Counsel (AGC) to the VA North Texas Health Care System on administering VA research funds supporting VA research.

#### **Determinations of the NRAC-SC**

The NRAC-SC recognizes that every VAMC is unique regarding the first GAO recommendation. The specific characteristics of individual VA facilities, academic partnerships, research portfolios, and other factors such as institutional culture, academic tradition, and areas of excellence vary widely and contribute to the unique quality of each facility's research partnerships. Moreover, although all VAMCs must operate under standard national VHA research policies, directives, and guidelines, their academic and NPC partners operate additionally under diverse local and state policies and regulations. Therefore, it is not surprising that a recurring theme in all stakeholder focus groups was the need for flexibility to maximize the research success of unique VAMC/NPC/AA partnerships.

In addition to flexibility, there was also a uniformly expressed need for well-developed lines of communication between all local institutional stakeholders and a common, clearly articulated, and well-documented understanding of shared missions, goals, and responsibilities to guide partnerships. The recommendations set forth by the NRAC-SC are offered to assist in improving decision-making and partnerships for VAMCs, NPCs, and AAs, while allowing them to retain sufficient institutional flexibility to leverage unique local strengths, adhere to diverse policies, procedures, and local/state regulations, and to respond to site-specific needs and challenges.

The NRAC-SC is providing examples and tools for partnering that have proven successful while avoiding overly prescriptive solutions that may work well at some sites but not others. Recommendations reflect the diverse experience and institutional backgrounds of the NRAC-SC membership and draw heavily from the vast experience of major stakeholder groups interviewed by the NRAC-SC, in addition to the review of the historical source documents.

Ultimately the recommended actions of the NRAC-SC are grouped into the following categories:

- Successful Practices:
  - Ensuring Understanding of the Overall Academic Partnership
  - Communication Mechanisms
  - Written Agreements
- Critical Needs:
  - Personnel Development
  - NPC Development as a Critical Partner
  - ORD Action Items

Each VAMC should identify ways to optimize relationships with their NPCs and AAs to enhance the mission of serving Veterans while recognizing the unique strengths and challenges faced by the individual partner institutions. The success of each endeavor depends on leadership expertise and commitment, resources, investigator talent pool, space, support services, and the motivation of all entities to collaborate effectively.

Regarding the second GAO recommendation (toolkit to help sites identify which entity should administer extramural research), the NRAC-SC identified two factors as key: where the work will be conducted, and which resources will be necessary for the conduct of the research. An additional consideration is identification of the institution which provides the best support for VA research investigators and enables VA investigators to meet the goals of the VA research. As the VA needs the support of other organizations to fulfill its research mission, these principles assist the VA in weighing alternatives and determining the best outcomes for VA research. When assessing the "best support," several factors should be considered, including but not limited to:

- 1) Access to VA research resources
- 2) Access to core laboratories
- 3) Necessary collaborators
- 4) Availability of inpatient and outpatient clinical research units
- 5) Eligibility for bridge and pilot project funding from the institution administering the research
- 6) Formal training opportunities for career development recipients
- 7) Availability of grant pre-and post-award infrastructure that can support VA-based investigators in the administration of extramural funding applications and awards

The VAMC should use the above-delineated principles to determine the administrative arrangement that best facilitates the likelihood of success and provides the best opportunity to benefit Veterans. The NRAC-SC has developed a Decision Matrix (Appendix A) that can help guide sites to develop written policies and agreements for local management of extramural funding for research conducted in whole or in part at the VAMC.

#### **Successful Practices**

#### **Ensuring Understanding of the Overall Academic Partnership**

Policy Memorandum 2, published in 1946 by the Department of Medicine and Surgery in the VA (which subsequently became the Veterans Health Administration), forms the conceptual basis for AA partnerships and relationships.<sup>5</sup> Relationships are synergistic, of mutual benefit, and are known to benefit veteran health care and VA's workforce. Academic relationships at their optimum have multiple parts, composed of business relationships in patient care (contracting, community care networks), workforce (shared and contracted faculty), education (integrated training programs and shared trainees), and research (shared faculty, research projects, space, and equipment).

Research projects often require collaboration of VHA, VA NPCs, and their AAs. As documented in the Westat and GAO reports, due to competing agendas and priorities, the administration of these collaborative research projects has become a matter of contention at some sites. As detailed earlier, the NPCs were authorized by legislation (1988) to serve as flexible funding mechanisms and partners to VA to facilitate research and education missions and successfully integrate the NPC as a valued partner within the long-standing AA relationship (38 U.S.C. §§ 7361-66). While a majority of VAMCs have long-term relationships with their AAs for some, and ideally all, of the benefits detailed in the prior paragraph, the NPCs are a relatively more recent entrant into the VA research enterprise and need to be brought into the relationship by VAMC leadership (see Communication Mechanisms for more on this topic).

Consistent with the Westat and GAO Reports findings, the NRAC-SC found that sites with successful partnerships had a broad and inclusive approach to the roles of the NPC, the VAMC, and the AA. These sites had a strong vision and understanding of the overall partnership across many dimensions (patient care, shared faculty, trainees and training programs, research) and an appreciation that individual contributors may gain in various complementary ways in different dimensions through such a global partnership. Conversely, research viewed in isolation from the other critical elements of the overall partnership was often associated with strong perceptions of "competition" for a limited pool of investigator-initiated funding. Therefore, success in building and maintaining healthy partnerships among VAMC, AAs, and NPC must maintain a broad focus on the strategic benefits of partnership writ large.

Even if focusing on the research domain itself, there is the opportunity to explore multiple elements that can lead to mutually beneficial, synergistic relationships if the focus expands

beyond the mere administration of extramural funding applications and the indirect cost (IDC) funding flows. Examples include the following:

- Agreements to utilize one partner's core services and/or facilities to benefit another partner's research program.
- Sharing of research staff with critical and specialized expertise to enhance the available research workforce of multiple partners (e.g., joint personnel agreements, intergovernmental personnel agreements, dual-appointed faculty/staff).
- Joint recruitment of clinical and non-clinical investigators in which the recruitment package can leverage what each partner has to offer (e.g., one partner may have "hard money" salary that is independent of grant funding to offer, but not space or start-up funds whereas other partners may be able to contribute in those dimensions).
- Joint applications for research funding where multiple partners' combined resources and capabilities make for stronger applications than what either partner alone could achieve.

Therefore, the NRAC-SC recommends that discussions among leadership at VAMC, NPCs, and AAs focus not only on administration of extramural awards but also include broad consideration of how each partner can contribute in multiple dimensions to research collaboration and resource sharing. Ideally, the discussions extend beyond the research domain to capture the full spectrum of an academic partnership as envisioned by the original authors of Policy Memorandum 2 in 1946. There are many examples where the NPC partner can, through its research and education missions, enhance the academic relationship and participate meaningfully in offering incentives for attracting and retaining dual appointed faculty.

#### **Communication Mechanisms**

Regular and inclusive communication among VAMCs, NPCs, and VA AAs is essential to effective partnerships across the three entities and fosters the inter-organizational collaboration needed to optimize research opportunities. The GAO Report noted that, at some sites, "VA medical center officials told us that poor communication with their AAs hindered their extramural research." The NRAC-SC confirmed this GAO finding and identified communication mechanisms that provide a number of important benefits such as the development of mutually beneficial collaborations and resource sharing agreements; joint planning for future expansion of the partnership; proactive management of decisions for administering extramural awards and understanding the impacts and resource needs of a given award on the partners; and, perhaps most importantly, communication with the jointly appointed investigators to make clear the benefits available to support their research at all partner institutions. Accordingly, the NRAC-SC recommends the following successful practices to sites that are seeking to further develop the VAMC/NPC/AA partnerships:

1) VAMC leadership should lead efforts to integrate the NPC partner into discussions in the collaborative undertaking. The NRAC-SC finds that it is incumbent on VAMC leadership, particularly those who, per VHA Handbook 1200.17, must serve as statutory members of the NPC Board (Medical Center Director, Chief of Staff, ACOS-R, ACOS-E), to proactively bridge the lines of communication from the NPC to the affiliate and establish a collaborative three-way dialogue. As noted by several NPC EDs, they often lacked direct influence with the AA in the absence of strong support from their VAMC Board Members. To quote one ED, "...the challenges are getting into this larger loop to fit the non-profit into that relationship...and then the NPC's limited ability to do that on their own. So, you really need the VA to initiate some of that interaction and bring the NPC into it."

2) VAMCs should establish routine communication practices across the three entities to incorporate regular meetings and foster the free flow of information. The NRAC-SC recommends that the NPC be incorporated into the Affiliation Partnership Council (APC). VAMC and NPC leadership should work with their AA to adopt these practices. Discussions should prioritize research-specific initiatives, addressing and overcoming shared challenges or barriers to collaboration, upcoming studies, and the development of mutually beneficial processes and agreements to facilitate and formalize the research partnership. For example, one site described a "Joint Operations Team" (JOT) comprised of representatives from NPC leadership, the VAMC Research Program (i.e., ACOS/R), and the affiliate Dean's office, that meets monthly to discuss and resolve emergent issues affecting the operations of one or more partners, obtain input or assistance from the others, and address issues involving dual appointed faculty. The group regularly reports back to the APC, which meets quarterly at this particular site. Moreover, the NPC ED has a non-voting seat at the table of the APC meetings, ensuring that the NPC's voice is heard.

As indicated in the linked <u>VHA Directive 1400.03</u>, while the APC is mandated under the Office of Academic Affiliations (OAA) policy for oversight and management of the shared education mission of VAMC and its AAs, OAA recently updated this policy to encourage expanded discussions at the APC in the area of research partnerships by requiring that the ACOS R&D serve as a voting member, and by encouraging NPC partners to be given a seat in that forum.<sup>7</sup> The policy also now promotes the formation of "subcommittees" similar to the JOT example described above.

- 3) Implement a system for reciprocal communication on pending grant applications involving a partner's resources. The GAO Report found that some sites had poor or no communication between the AA and the VAMC and NPC when VA resources or veteran patient recruitment were a key component of a joint investigator's extramural funding application. The NRAC-SC confirmed this finding in its stakeholder focus groups. For example, as noted by one ACOS/R:
  - "...when grants are being funded...I keep arguing with [the affiliate] that the VA needs to be on the front sheet of these things and the NPCs so they can run a subaward through the nonprofit to recruit veterans for their study. And all of a sudden, they come in after [saying] oh, we can't do that now, but we still want to be able to recruit veterans. Of course, we still want veterans to have access to clinical trials. But it just seems [hard] to get them trained—their reluctance to be trained that we need to come in much sooner than after the study has been opened."

The NRAC-SC found that successful sites have a mechanism for proactive communication of pending award applications, regardless of which site is identified as the appropriate administrator of the prime award, to ensure that the resource impacts at the partner institutions are fully understood, and that appropriate subawards are in place when indicated to cover costs of those resource impacts. The NRAC-SC recommends that such proactive and reciprocal communication between AAs, the VAMC research program office and the NPC be developed at all sites to ensure that VAMC impacts are accounted for in the final arrangements made for a given award. The system should promote coordination of award management, including sub-awards, with focus in particular on the 1/3 of sites found in the Westat Report to lack subaward agreements from the AA to the NPC for work performed at the VAMC.

4) Educate investigators and departmental grants administrators on the policies or agreements governing where extramural funding is administered. Ideally, all partners (VAMC/NPC/AA) proactively and consistently communicate policies and agreements for how extramural research performed fully or partially at the VAMC is to be administered. However, the Westat Report, GAO Report, and NRAC-SC stakeholder focus groups all documented a number of

cases where this does not routinely happen. Even when formalized agreements are in place, certain departments at the affiliate or new departmental grants/contracts staff are not always informed of the existing agreements. For example, one NPC-ED noted that "I have grants managers...calling me from all over the university, and they don't know who we are. They don't understand the NPC's structure – so every time we engage with yet another department at the university, there's an education process of who we are and why they need to do business with us...". The NRAC-SC recommends, therefore, that when agreements have been established, VAMC research staff and NPC leadership work proactively with their AA partners to ensure consistent communication of the policies and agreements already in place. This ensures that all units within the AA including the dual appointed investigators themselves are fully aware of these agreements and how they are to be applied.

## **Written Agreements**

Both the GAO Report and the Westat Report documented the existence of various written agreements at sites with successful affiliate research relationships. These agreements include those mandated by VHA or other federal policy, such as a Memorandum of Understanding (MOU) when the VAMC seeks to utilize the research oversight committee of the AA to serve as its committee of record (e.g., Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee); these also include the NIH-mandated MOUs documenting the VAMC and affiliate effort components comprising a dual appointed investigator's combined effort and salary across the institutions. Others, while not mandated, facilitate collaborative benefits, including:

- Joint Personnel Agreements (JPAs) where the NPC can reimburse the affiliate for all or part of the salary and benefits of an affiliate employee providing effort to an NPCadministered extramural award.
- Agreements for access to core resources and services offered by a partner institution, with some sites extending so-called "on campus" rates to the partner institutions.
- Shared purchasing agreements, where the NPC or affiliate partner may agree to pay for ongoing maintenance contracts for VA-purchased equipment to which investigators at the partner institutions have access.

Sites with successful partnerships also frequently had formal written agreements in critical operational dimensions such as dual appointment policies and procedures, formalized communication in cases of alleged noncompliance/misconduct of a dual-appointee, shared oversight and resolution of noncompliance/misconduct allegations, and mechanisms for appropriate administration of extramural awards. GAO, Westat, and NRAC-SC found these formal written agreements to be less common than the other examples cited above.

A frequent observation in the Westat Report and the NRAC-SC focus groups was that long-standing academic institutional standards and expectations for faculty promotion, tenure, securing of research space, and coverage of university salary pressured the submission of extramural awards through the AA. Sites with more clarity about when the NPC would administer extramural grants (whether by the preponderance rule, sub-awards to the NPC for VA work, or some other agreement) typically had mechanisms in place for crediting research productivity at the VA as part of the promotion and tenure process for university faculty. The American Association of Medical

<sup>&</sup>lt;sup>e</sup> Such written agreements must of course be consistent with federal and state laws, VA and university policies and regulations, and should be developed with the review and concurrence of legal counsel for all parties involved.

Colleges (AAMC) stated that "administration of an award by the NPC versus the university should have no effect on faculty promotion and tenure."

Frequently superimposed on the perceived pressures created by tenure/promotion processes was the observation that AAs were reluctant to allow NPC administration of extramural awards (particularly from the NIH) due to the relationship of grant administration to national rankings for research. However, even the largest and most successful NPCs administering extramural funding have an annual budget of about \$20-50 million; this usually equates to a minor percentage of the AA's annual extramural funding portfolio. Therefore, at sites where AAs have very mature and extensive research programs, even a highly successful NPC administering extramural awards is not likely to significantly impact the affiliate's national research rankings. However, NRAC-SC recognizes that for sites where the AA has a limited research funding portfolio and is actively trying to grow, the VAMC and the NPC must work with the AA to establish paths for mutual benefit. This again points to the need for flexibility in developing suitable agreements that balance the individual needs, strengths, and challenges faced by the individual partners at the local level.

It is not surprising, therefore, that in response to the question "should there be formal policies and agreements that specify the process for administration of extramural research grants by the AA and NPCs?" the NRAC-SC heard a consistent message from all four stakeholder groups (Medical Center Directors, ACOS/R, NPC EDs, and Affiliate Partners) that there should <u>not</u> be a nationally mandated uniform policy statement to which all sites must confirm. This echoes the GAO-noted challenge of "maintaining needed flexibility." However, all stakeholder groups were equally consistent in their support for template documents that could be reviewed and adapted as necessary to meet the local needs:

"I would say absolutely it would be helpful to see examples of best practices in which this works that can be then adopted by other local Universities and VA systems...if there's something on paper that people can look at and adapt, that would make an enormous difference to overcoming the inertia to creating all the agreements from scratch." (AA Dean for Research)

"I agree. I wouldn't want to be tied to a specific policy because sometimes we have to have flexibility. But as long as you're saying, these are suggested activities or best practices, and that's communicated in the guidelines, I think that's a terrific idea." (ACOS/R)

"It is imperative to have something in writing. As we've sort of talked about, it really helps to have some top down, and I think that putting something in writing and having the leaders in each of the three entities signing it is really important. But what I also think is really important is to recognize that it's not going to be one-size-fits-all for all NPCs, and I think that each NPC and each affiliate and each VA while maybe with some guidance, centrally, is going to have to figure out what works best for them." (NPC ED)

"But one of the benefits, I think, of putting these kinds of policies and agreements in place is it helps with that education process to let folks understand how these can be used; where it's appropriate to use for the NPC versus the affiliate, and then, in regards to the prior question, whether or not folks even understand what those processes are for...there's a lot of education that has to happen here, and this is one way to do that." (MCD)

The NRAC-SC requested examples of written agreements from stakeholder groups that address a range of operational dimensions of a healthy VAMC/NPC/AA partnership. With review and concurrence from VA OGC, these templates will be available to all sites through the website that formalizes the response to the GAO recommendation for a toolkit.<sup>8</sup>

With respect to administration of extramural funding, one successful type of extramural administration formula cited by the Westat Report and discussed by stakeholders is the "preponderance rule," which holds that the entity where the majority of research work is being performed should be the organization that submits the proposal and administers the award. Another common successful practice was the appropriate use of legally approved sub-awards from affiliate to NPC for the VA portion of the research, especially when the NPC was not adequately resourced to provide full pre-and post-award support for prime grants. Sub-awards can also be used by the NPC acquiring necessary research support services from the AA. Lastly, in some cases, the mechanism of choice depends on the funder of the research grant, such that for some funders, the agreement is a preponderance rule and for other funders, agreement would be to utilize sub-awards:

"So we basically have...a policy that says when 50 percent or more of the work is conducted at the VA that we administer the award and then we subcontract to the university. This policy ... applies to everything but NIH. That was sort of our give and take with the university. We were trying to maintain our good relationship and basically agreed that...the NIH awards would stay with the university, and we would just subcontract with them."

In summary, the NRAC-SC encourages VAMCs and their NPC and AA partners to utilize examples of vetted written agreements that codify key elements of successful research collaboration. At a minimum, these must include agreed-upon mechanisms for the appropriate administration of extramural awards that contain VA research components and could consist of mutually agreed-upon policies and procedures for elements including but not limited to:

- 1) Sharing of space/equipment/core facilities.
- 2) Dual appointment policies and procedures.
- 3) Communication on compliance issues that may affect other partners.
- 4) Extension of internal "institutional" rates for core services to investigators using funding from one of the partner institutions.

In addition, VAMCs and their partners should ensure that the local agreements are communicated to, and understood by, the shared group of investigators.

#### **Critical Needs**

# **Personnel Development**

Partnerships across VAMCs, NPCs, and AAs are strengthened when personnel are well supported at both individual and institutional levels. The NRAC-SC focus groups with individual stakeholders identified a critical need for specific development of leaders across all domains of the research partnership, especially at sites where the partnership is limited and not operating effectively. For example, a research leader from an AA stated, "a training program for the actual leaders, these people that are signing these affiliations, would be wise and vital." Therefore, the NRAC-SC recommends that:

- 1) VAMCs and NPCs leverage formal career development support and mentorship programs for new NPC EDs and ACOS-Rs, through the NAVREF Executive Director Mentorship Program and ORD ACOS-R/Administrative Officer (AO) Mentorship Program, respectively.
- 2) ORD and NAVREF integrate successful practices for enhancing partnerships such as those recommended by the NRAC-SC into their training programs.

- 3) The toolkit<sup>8</sup> initiated by the NRAC-SC serve as an accessible and every-expanding document repository to house sample documents, guidance documents, agreement templates, and approved processes available to ALL stakeholders, not just VA.
- 4) Sites engage in joint VA/NPC/AA recruitment by:
  - a) Involving VA Chiefs of Staff (COS) and ACOS-Rs in decision-making when coordinating collaboration between new AA faculty members who may have dual appointments with VA.
  - b) Engaging the NPC in the new faculty member onboarding process. NPCs should consider if they can contribute start-up funds or other advantages to encourage new researchers.
  - c) Standardizing integrated (AA, VAMC, and NPC) orientations of new Principal Investigators (PIs) during their first 30 to 90 days.
  - d) Communicating to new and existing dual appointed researchers the advantages of dual appointment, ways to leverage the VA/NPC/AA partnership, and their role in the AA and VA research missions.
  - e) Obtaining commitment from AAs to accept and recognize VA research achievements for promotion.
  - f) Working with VISN partners to consider startup packages for new junior faculty (e.g. VISN-run Career Development Awards).

Both ORD and NAVREF currently offer mentorship programs for new ACOS-Rs, Administrative Officers in Research (AO-Rs) and NPC EDs, respectively, where individuals who have been in the same roles at other sites serve as mentors. The NRAC-SC recommends that each of these mentorship programs be expanded to include specific mentorship in the development of successful research partnerships and that the audience is expanded to include not just those new to their VAMC or NPC leadership roles but also existing ACOS-R and NPC EDs from sites that are struggling to establish effective partnerships with each other or their affiliate.

In addition, jointly recruited and appointed investigators who are invested in the shared missions of all partners ensure that an overall understanding of the shared mission extends beyond leadership and throughout the shared faculty. Dual appointed faculty are the backbone of the collaborative clinical, educational, and research missions. A key AA focus group participant stated, "I think the number one practice...is when folks have joint appointments, not [just] affiliate, but actually have paid roles in both facilities...because that is seen by both sides as being core to their mission and important." While this may not be practical for every clinician or non-clinician investigator within a given university department or VA service, a core of dual appointed faculty within each unit ensures better mutual understanding.

Along these lines, the NRAC-SC noted that many sites with successful partnerships engaged in frequent joint recruitment of new non-clinician and clinician investigators by leveraging what each partner can contribute, including recognizing where the NPC can assist in the recruitment. The results of a survey conducted by members of the NRAC-SC representing both the ACOS-R community and NAVREF in preparation for a workshop on joint recruitment at the 2021 joint NAVREF/ACOS-R/AO-R virtual conference, and made available to the NRAC-SC, noted that:

1) Over 80% of ACOS-R respondents reported active involvement in joint recruitment with the affiliate, but only about 42% of NPC ED respondents reported involvement.

17

<sup>&</sup>lt;sup>f</sup> Where necessary, OGC Ethics should be consulted to ensure the proposed dual appointment is consistent with all federal policies and regulations.

- 2) NPC EDs reported that the most common reason for NPC lack of involvement in joint recruitment was that the AA and VA did not allow the NPC to participate.
- 3) Where VAMC and/or the NPC did actively participate in recruitment, each partner was often able to bring unique contributions to the recruitment package that made the sum much more than the individual parts:
  - a) The VAMC was most likely to contribute FTE/salary (VA "8ths"), space, and equipment, with start-up funds, relocation costs, and administrative support somewhat less common.
  - b) The AA was most likely to contribute start-up funds and FTE/salary, space, equipment, relocation costs, and administrative support.
  - c) When involved in the recruitment, the NPC reported start-up funds, relocation costs, equipment, and administrative support as the most common contributions made to a recruitment package.

To optimally leverage the resources of all partners in the faculty recruitment process, the NRAC-SC recommends that VAMCs make active efforts to integrate their NPC partner into the joint recruitment process. And new dual appointed researchers should understand the advantages of dual appointment; this understanding leads to investigators who are fully invested in the shared partnership, rather than seeing themselves as primarily a member of one institution that might pay the majority of their salary.

#### **NPC Development as a Critical Partner**

NPCs can have certain advantages in administering extramural funding for VAMC researchers. Generally, they can administer an award at an indirect cost rate lower than the academic partner. Also, many have long-established, successful track records of outstanding customer service to the Principal Investigators (PIs). The Westat Report and GAO report each highlight success stories where NPCs manage robust and diverse extramural portfolios (e.g., federal, industry-sponsored and smaller foundation awards) through effective partnerships with both the affiliated VAMC and AA. The NRAC-SC focus groups established that these sites typically have a well-established administrative infrastructure to provide support to their PIs at a level comparable to what those investigators can expect from their academic institution. At some NPCs, subawards from the AA are the primary mechanism for supporting the VA-based research of the dual appointed PIs, whereas a more limited number of NPCs serve as the prime administrator of extramural federal awards.

However, smaller NPCs are not as well-resourced due to a more restricted grant portfolio (often limited to industry-sponsored trials and smaller foundation awards with smaller [< 10%] IDCs available). This in turn constrains the funds available for administrative infrastructure necessary to provide effective support to the PI in key areas such as pre-award grant submission, post-award grant administration, budgeting, staffing, etc. It must be recognized that even the largest and most successful NPCs did not begin with large administrative staffs, and often developed their current diverse portfolio gradual over a number of years. Therefore, the NRAC-SC encourages such NPCs to consider the following developmental steps to maximize their ability to contribute as a partner in the overall VA-NPC-AA relationship:

 Development of a Plan for Gradual and Sustainable Growth. NPCs may benefit from investing in building capacity and expanding resources (i.e., staff) at a steady pace over time to demonstrate enduring capabilities to Pls, and in turn Pls are positioned to see that the NPC can support their pre- and post-award work – a mutually beneficial connection. In the PACER conference response to the Westat Report it was noted:

"Even with a big program, you have to manage the fluctuations in grant revenue. There is no margin in grant awards, so the NPC may have to let staff go to manage these fluctuations. You also have to manage the awards to assure that the project is spending the direct project funds or, you don't get the Facilities and Administrative Costs (F&A) [i.e. IDC] to support the NPC. It is imperative to be able to project income, so you can plan for staffing needs and make adjustments as needed...In getting started, you need a gradual process to ensure there is enough money in the bank. You need infrastructure. Pre-award costs money to do. There is not a straight line of success. You need good forecasting models and the right people hired that can do this. You need to know the number of current awards, the number of submissions expected, and the history of funding success. Sometimes it takes going into deficit state to invest in future. This is much harder to do in small programs where they don't have much cash on hand." (PACER Report)

Accordingly, the Decision Matrix (Appendix A, see also ORD Action Items, #5) developed in response to recommendation #2 of the GAO Report incorporates a determination of adequate resourcing of the NPC to effectively provide service to the PI, in the best interests of accomplishing the scientific intent of the funded project, and thereby best serve the VHA research mission. Ideally all NPCs, through appropriate development of their core administrative infrastructure in a progressive fashion, can begin to answer this decision matrix question in the affirmative for an ever-growing range of funding opportunities.

Through NAVREF-sponsored mentorship initiatives, developing NPCs can rely upon sites that have already successfully navigated such a progression in their research portfolio, and associated administrative infrastructure. For sites that are seeking to establish an NPC for the first time, it may be advisable to seek to have another NPC with established infrastructure serve as the facility's NPC, at least initially, under a multi-site NPC arrangement. There are a number of successful examples of such multi-site NPCs, and this can provide access to existing infrastructure, until such time as the facility's extramural research portfolio is of sufficient size to warrant potential establishment of their own NPC with adequate infrastructure to serve their PI base.<sup>9</sup>

A potential impediment to progress in expanding the NPC extramural research portfolio, is resistance from the AA to allow the NPC as an administrator of federal extramural awards for investigators with both VA and affiliate appointments. To overcome that obstacle, the NPC needs to ensure the support of their VA partner to facilitate the implementation of the successful practices highlighted earlier in this document. A quote from an NPC ED, echoed repeatedly by others, illustrates this critical need:

"We must invest in development of our grants management, otherwise our reputations are at risk. And so that's a threat, I think, to the nonprofits, in that if there isn't the competence there in grants management then we can do all this work and invest all this time and money, but we must find ways to develop that level of knowledge at the nonprofit level because we're only as strong as our weakest link. Federal grants are extraordinarily complex, and I think that if, you

embarking on a given strategy.

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<sup>&</sup>lt;sup>9</sup> NRAC-SC recognizes that formation of a single site NPC, joining a multi-site NPC, and transitions between the two (from single- to multi-site or vice-versa) is a complex process, with specific standards set forth in wir 1200.17 that must be followed. Consultation with the ORD Non-Profit Program Office, NAVREF, and sites that have successfully made these transitions are highly encouraged before

know, there are NPCs that are more than capable to do it, and there are NPCs that are going to need to build that before they're going to be able to administer grants. If we move things over quickly and say... grants are going to be administered at the NPCs and we [mess] it up, that's it, ... they're never going to come back again. So, I think that is one of the most important things."

2) Improve Awareness of NPCs Through Outreach. In addition to the steps needed to develop as an effective partner and administrator of extramural awards, a frequent theme identified in the reports and focus group discussions was the need to improve awareness of NPCs and the strengths of working in partnership with them:

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

Additionally, awareness of NPCs and their ongoing research opportunities affects growth and success, including recruitment, development, and relationship-building. When interviewed by Westat, an Executive Director captured this need as it pertains to engaging research clinicians, stating:

"I think, when I got here, we were kind of a well-kept secret, and I don't think a lot of energy was given toward bringing in new Pls... so one of our responsibilities that I see is getting it out there.... If you think you're interested in research, we're willing to work with you. We're willing to help train you. We're willing to facilitate what you need to do research because we realize you've got this heavy clinical load also."

To increase such awareness, NPCs must work to avail themselves of the opportunities to join the dialog between VA and AA through implementation of the successful practices highlighted under Communication Mechanisms. Regular communication with the VA Research Service via the Administrative Officer for Research (AO-R) and ACOS-R regarding infrastructure and facility needs in clinical and basic research services can be key to timely, consistent collaboration. VAMC relationships can be leveraged to communicate with key stakeholders at AAs and within the local community. They may also be leveraged to build relationships with other local VA services necessary to support research activities, such as Clinical Services, VA Human Resources and VA Office of Information and Technology.

Within the tri-partite VAMC-NPC-AA relationship, a key to success is that NPCs are appreciated as well positioned to support the research of VA investigators. The Successful Practice "Communication Mechanisms" offers a number of concrete examples for achieving this goal. In addition, VAMC and NPC partnerships can work to increase visibility within AA settings through awareness campaigns highlighting successful PIs and growing these campaigns organically. Success stories of the three-party partnership can also be

communicated with the NPC's Board of Directors, the broader VA research community, and VA leadership outside the immediate sphere of the Research Program.

Finally, the NRAC-SC recommends a national dialog involving ORD, NAVREF, and AAMC to bring all partners to a better understanding of the benefits of a robust tri-partite partnership (see below section Critical Need "ORD Action Items" for further details).

3) Developing the NPC Investigator Base through Outreach. NPCs may also wish to prioritize relationship-building opportunities/activities with PIs, to facilitate pre-award communications and goal setting, and promote NPC inclusion in PI planning activities and forecasting. The dissemination of NPC PI success stories as noted above will broadly support an established NPC presence in the AA relationship. Efforts should be made to promote awareness of such success to the broader VA PI community and to educate and inform investigators who have not yet worked with the NPC about the relationships, benefits, and responsibilities for VA, NPCs, and AAs. As noted in the ACOS-R/ACOS-E response to the Westat Report:

"What makes an NPC successful is being linked to a VAMC that promotes research so that PIs can get grants. The NPC must maintain a good working relationship with its VA Research Office. Having a cooperative [AA] is also helpful. Maintaining positive relationships with and support for a sufficient pool of investigators who obtain research grants and [Cooperative Research and Development Agreements (CRADAs)] is essential to generate funding for the NPC."

Efforts to develop and maintain such positive relationships depend upon an active outreach program.

#### **ORD Action Items**

The NRAC-SC determined that ORD's attention to certain key areas will significantly improve relationships between VAMCs, NPCs, and AAs. The NRAC-SC, therefore, recommends that ORD take the following actions:

- 1) Establish national enterprise-level communication with affiliates and the NPC community. Currently, ORD promotes enterprise-level solutions among its VAMC stakeholders to enhance the execution of the research mission at a national level. This enterprise-level approach should be expanded to include an ongoing active national dialogue with NPC and affiliate partners. NAVREF and AAMC can be included as key partners to leverage their existing relationships with their NPC and AA stakeholders, respectively. This national-level dialogue will assist AAs in understanding the core VHA research mission, how that mission can synergize with the affiliate research mission, and the crucial role it plays.
- 2) Develop a Research Collaboration Agreement template. For decades, affiliation agreements have existed within VHA. The standard affiliation agreement is an educational program agreement that sets out respective responsibilities for both the VA and the AA. These templates are executed through OAA policies and OGC-approved agreement templates. The NRAC-SC found that successful research sites often had written agreements with their affiliate, sometimes including the NPC as well, to cover key elements of the research partnership such as sharing of space, equipment, and core facilities, dual appointment policies and procedures, compliance issues, and mechanisms for appropriate administration of extramural awards (see Document Templates for further details). Unfortunately, this practice

is far from universal. As one affiliate partner notes, "everyone has their own personalities and other issues, but if there's something on paper that people can look at and adapt, that would make an enormous difference to overcoming the inertia to creating all the agreements from scratch." Therefore, NRAC-SC recommends that ORD develop a Research Collaboration Agreement template in collaboration with OGC, similar to the templates developed for educational purposes by OAA and OGC.

- 3) Authorize and promote research relationships with entities other than the site's education affiliates. Certain VAMCs are quite remote from their AA, making research at both facilities logistically challenging for dual appointed faculty and reducing many of the shared benefits of research collaborations (e.g., space, core services). However, another more proximal university may make a more logistically effective research collaborative partner, and ORD should both authorize in policy and promote such partnerships to benefit the local VAMC/NPC research program.
- 4) Communicate guidelines and practices to the field to remove perceptions of obstacles to collaboration. The NRAC-SC asked all stakeholder groups to identify challenges and obstacles detrimental to successful collaborative partnerships. The NRAC-SC noted that some of these challenges would require further national efforts to resolve, including but not limited to:
  - a) Revisiting the scope of VA research training requirements in light of similar training from the affiliate.
  - b) Updating or re-establishing national guidance for research protected time on the VA side to ensure researchers can accomplish the VHA research mission through dedicated time allocations.
  - c) Continuing to advocate for relief from the statutory requirement for a one-year break after a four-year Intergovernmental Personnel Agreement (IPA) term because the VHA research mission often benefits from the expertise of scientists whom other institutions employ.

ORD is already aware of these ongoing challenges and working to address them in many cases; The NRAC-SC recommends ongoing efforts in these areas to remove perceived or actual impediments to successful research collaboration and partnership. The NRAC-SC found other challenges noted during the stakeholder meetings to involve local misconceptions or incomplete understanding of national VHA policies, including but not limited to issues of data sharing, inconsistencies in local VAMC HR application of VA excepted hiring authorities for research personnel, and lack of consistency in communication and application of shared Intellectual Property (IP) rights, and ORD should disseminate clarifying guidance to overcome these misconceptions among VA partners..

- 5) Host, maintain and continue to develop/expand the online toolkit repository for successful research partnership practices, documents, and templates. Along with this white paper, a key charge of the NRAC-SC was to establish a toolkit resource for VAMCs and their NPC and academic partners to facilitate establishing, maintaining and growing successful partnerships. The toolkit, per GAO recommendations<sup>1</sup>, was to include "a decision tree and successful practices, to help local VA medical center officials decide which entity—NPC or AAs—should administer extramural funding based on providing optimal support for research." The NRAC-SC recommends that ORD satisfy this requirement in the following ways:
  - a) Establish and maintain a broadly available internet (not VA-intranet) repository of guidance documents and approved template agreements drawn from the recommendations and examples gathered by the NRAC-SC, and from guidance already published by or otherwise available to ORD.

- b) Ensure the toolkit provides guidance documents and templates that encompass the broader view on the strengthening of research relationships overall as defined throughout this white paper, rather than focusing more narrowly on the issue of who should administer extramural funding, which is but one key element of a successful partnership.
- c) Maintain the toolkit repository, ensuring it is kept up to date and updated as new guidance becomes available and new successful practices are identified to ensure that it becomes an ever-expanding resource. For example, the ACOS/AO listserv discussions often identify key successful patterns at specific sites in response to questions or challenges at other facilities. These discussions should be actively monitored and utilized to update the online toolkit as warranted.
- d) Maintain links to the NAVREF website within the toolkit repository and possibly the AAMC website so that all key partners (VA, NPC, AA) can benefit from the information provided. Moreover, as NAVREF identifies successful practices from surveys or reports from its NPC members, those practices can also be incorporated into the master Toolkit.

Regarding the GAO call for a "decision tree," the NRAC-SC has developed a Decision Matrix that details key decision factors in evaluating and determining how extramural funding can best be leveraged to provide optimal support. This upgrade achieves the intent of the GAO recommendation while recognizing that a "decision matrix" might better preserve the flexibility needed in the field, as emphasized by all stakeholder groups interviewed.

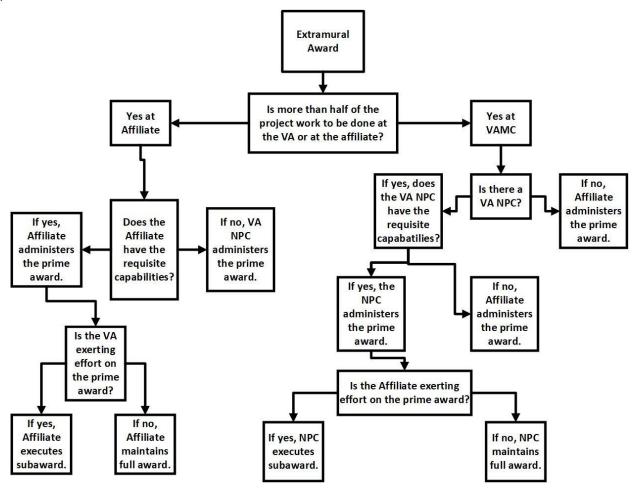
#### Conclusion

In summary, the NRAC-SC has identified six domains of action that will enhance and improve research relationships. Although this NRAC-SC's charge in responding to the GAO Report relates explicitly to the VA research enterprise, it is important to recognize that the research mission cannot be addressed independently of the VA's clinical and educational missions. While three separate organizations (VA, NPC, and AA) represent individual pillars of a strong research enterprise, their functions are intertwined and inter-related. Moreover, the clinical, educational, and research enterprises typically function best in an academically robust environment where all three missions are well supported, coordinated, and accompanied by a culture of excellence and inquiry.

The NRAC-SC's engagement with stakeholder groups identified that the key to successful, robust partnerships is a full appreciation by all partners of the collective contributions made by each partner across all key domains (clinical, educational, and research) rather than an isolated focus on just the research mission and who should administer extramural awards. VA facilities seeking to grow their overall partnership and integrate their NPC into the partnership should ensure that they are emphasizing the overall partnership's shared mission across all of these dimensions.

# **Appendix A: Decision Matrix for Handling of Extramural Awards**

A common mechanism for administering extramural grant funding is through the "preponderance rule" – the understanding that a grant is administered at the institution where most work occurs. NPCs and AAs may use this rule when determining which entity should administer extramural grant funding. However, final decisions may differ locally depending on real-time constraints and considerations. It is strongly recommended that the VAMC, NPC and AA have in place a written agreement that details how extramural grants will be administered with respect to prime award administration, subaward mechanisms and criteria for implementation, etc.



<sup>1</sup>Applicable Considerations:

- Access to VA research resources
- Access to core laboratories 2)
- Necessary collaborators 3)
- Availability of inpatient and outpatient clinical research units

- Eligibility for bridge and pilot project funding from the institution administering the research
  Formal training opportunities for career development recipients

  Availability of grant pre-and post-award infrastructure that can support VA-based investigators in the administration of extramural funding applications and awards

<sup>2</sup>It is recommended that NPCs work to gradually develop an infrastructure that can lead to increasing capability to serve as an administrator of prime- and sub-awards over time. For VAMCs that do not yet have an NPC, joining a multi-site NPC partnership may provide necessary resources on an interim basis.

# **Appendix B: Works Cited**

- 1. GAO, Veterans Affairs Research: Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and AAs, GAO-20-570, July. 17, 2020, Washington, D.C. The vast majority (91% in FY2019) of this extramural funding was administered by the NPCs and AA partners of the VAMCs conducting extramurally-funded research. It was further noted that intramural and extramural research funding levels were nearly identical in FY2017-2018, with extramural funding still accounting for about 46% of all expenditures on VA research in FY2019 according to the VA's annual Research and Development Information System (RDIS) report. Therefore in the time period sampled (FY2017-2019) extramural funding administered by VAMC partners had nearly equivalent weight as the VA's intramural research appropriation in supporting the output of the VA's overall research program.
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