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Rachel B. Ramoni, D.M.D., Sc.D.
Chief Research and Development Officer (CRADO)
Office of Research and Development
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Re: Study on Veterans Affairs Extramural Funding, Final Report Submitted by Westat, 2018

Dear Dr. Ramoni,

The Association of American Medical Colleges (AAMC) appreciates the opportunity to offer feedback and recommendations related to the September 2018 Study on Veterans Affairs (VA) Extramural Funding submitted by Westat to the VA Office of Research and Development (ORD).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 VA medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

For more than 70 years, the VA has partnered with U.S. medical schools and teaching hospitals to improve access and quality of care for our nation's veterans. Approximately, seventy percent of VA physicians have dual appointments in academic affiliate medical centers. VA-academic medicine research collaborations are critical to fostering veteran-centric research and improving current and future healthcare for veterans and all Americans in all health care settings.

AAMC supports the steps VA ORD is taking to better understand how extramural research funding is administered. Specifically, VA ORD's commissioning of the "Study on Veterans Affairs (VA) Extramural Funding" provides VA with an opportunity to determine whether improvements to the current process are necessary to further advance VA research and its overall benefit to veterans. The Westat report provides an important foundation for VA ORD to better understand the current perspective of VA and NPC staff, which can be built upon to inform and support VA researchers. AAMC identified several topics that we believe would benefit from further action or analysis by ORD.

- 1. Because the Westat report did not include the perspectives of the academic affiliates, the AAMC recommends that ORD perform additional interviews with these important partners about their experience with VA research. These discussions should also include information regarding the research-related services affiliates provide to the VA.**

The report details the decades-long relationship between VA Medical Centers (VAMCs) and academic affiliates; however, Westat's report presents interviews only with executive directors from the nonprofit research and education corporations (NPCs) and VAMC Associate Chiefs of Staff (ACOS) for Research and Development. While eight of Westat's preliminary case studies included academic affiliates, neither the findings nor any quotes from the affiliates perspective we're included in the final report. The unilateral nature of the 83 in-depth interviews is particularly important to note because the study results are based on these interviews, and the views were not balanced with the perspectives of staff from academic affiliates. ACOSs may have joint appointments, but their salary is predominantly or fully funded by the VA. Therefore, the report has too narrow a perspective and is not representative of the full enterprise contributing to VA research. To broaden the scope of views, ORD should interview additional representatives from the academic affiliates, such as the Deans of Research and the Principal Business Officers, and present those findings.

The AAMC recommends that ORD compare and contrast services typically provided by the academic affiliates and the NPCs. The AAMC believes that presenting additional interview responses to the following questions, which were included in the survey instrument but not in the final report, would help to illustrate capabilities of both the academic affiliates and the NPCs:

“What are some functions that affiliates perform that NPCs do not?”

“Are there some functions that academic affiliates perform more effectively or efficiently than NPCs?” *Study on Veterans Affairs (VA) Extramural Funding, page A-8*

- 2. AAMC recommends that each VAMC engaged in research should develop formal written policies that outline the process for administration of extramural research grants.**

The report states:

“VAMCs tend to fall into one of three groups with respect to submission policies applicable to VA investigator grants. These groups are: VAMCs with formal written policies (23 of 78); VAMCs with unwritten informal guidelines (20 of 78); VAMCs without a policy or guidelines and where PIs make the decision (35 of 78).” *Study on Veterans Affairs (VA) Extramural Funding, page 3-33*

These local VAMC-generated policies should prioritize the best interests of veterans and facilitate appropriate conduct and outcomes of research projects. Given the variability in research resources and capabilities, policies at the local level will clarify misunderstandings regarding the

practices and roles of both the NPCs and academic affiliate. Local policies should be created that enhance NPC, research partners, investigator, VAMC, and institution collaboration and understanding of their respective roles and responsibilities and reduce perceived conflicts of interest.

3. The AAMC recommends that ORD enhance education for VA staff and researchers about the intended purpose of NIH F&A reimbursement and Veterans Equitable Resource Allocation (VERA) in offsetting the operating costs institutions incur as a result of conducting research. This would help clarify points of confusion raised in the Westat report.

The report states:

“The majority of interviewees reported that the affiliate does not use the indirect fee to benefit the VA. About one-third of interviewees explained that the affiliate uses the indirect fee to pay for resources at the university, which benefit the research enterprise of VA research conducted at the affiliate.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-72*

“Since NPCs cannot claim facilities fees as part of their indirect costs ... their overall overhead is lower than that of most academic affiliates, who require both facilities and administrative (F&A) fees.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-79*

The interview results, and Westat’s interpretation of the quotes included in the report, suggest that there is often a misunderstanding regarding additional costs associated with NIH grants. NIH guidelines (and Office of Management and Budget [OMB] regulation) describe F&A costs as “those that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity.”¹ Examples of costs include the support of core facilities and maintenance of research infrastructure.

NIH reimburses institutions above the directly attributed costs of a specific research project through F&A reimbursement to support costs of the maintenance to the infrastructure needed to do the research work. F&A charges have been included in federal grants since the 1940s, and these reimbursements recognize that institutions have expenses related to research projects that may not be directly attributable project by project. For example, a lab requires heat, lights, power, water, internet access, a roof, janitors – and attributing these line-item by line-item on each grant would lead to a confusing and expensive administrative process. In other words, it would require, for example, calculating how much of an institution’s overall water bill should be attributed to one specific grant.

¹ “Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education.” OMB Guidance. 2 CFR Appendix III to Part 200.

The federal government defines a fixed set of expense categories and reimburses institutions for these expenses after evaluating the institution's real costs and negotiating a reasonable rate. The resulting calculation allows the funding agency to deal with multiple grants at an institution through a single F&A rate, rather than requiring a cumbersome grant-by-grant negotiation.² Those F&A charges are broken down into two categories, facilities costs and administrative costs. Administrative costs for universities—which include paying for staff to ensure compliance with regulations and other obligations—are capped at 26%, while facilities costs do not have a similarly fixed limit.

The first step in determining the F&A charges occurs when an institution negotiates with the government regarding which institutional costs can be reimbursed. The method is standardized, and there are nine categories of expense (e.g., general administration, equipment and building depreciation), each of which must be well justified in the negotiation process. Once an F&A rate is established (on average 50-60% for universities), that rate is multiplied against the allowable direct charges in the grant (referred to as the "Modified Total Direct Cost" or MTDC) and the previously determined F&A charge. For example, if a \$100,000 grant was awarded to Stellar University, which has a negotiated rate of 60%, Stellar would receive \$60,000 to provide support and resources for the research operating costs, above what is being paid for the direct costs of the research. Those direct costs include salaries, reagents, laboratory supplies, animals, and the like. In this illustration, the total cost of the grant from the NIH is \$160,000, roughly two thirds of which goes to the direct costs of the research and one third to F&A reimbursements. F&A charges are reimbursements for a collection of expenses and reflect real costs to the institution. F&A rates are re-negotiated with the federal government on a periodic basis.

According to the report, "About a third said that the affiliate uses the indirect fee to pay for resources at the affiliate that benefit the research endeavors of dual appointed VA PIs who run their projects at the affiliate." In fact, what this means is that the institution is using its own resources to invest in support for VA research. Additionally, for most universities, the costs associated with the administrative portion of the F&A charge usually exceed the 26% limit. The university then must cover the remaining costs through other sources like philanthropy, tuition dollars, state funds (at public institutions), or transfers from clinical operations. Because neither direct grant charges nor F&A reimbursements cover issues like unfunded faculty effort, gaps in funding (i.e., paying the direct costs of a research project when there's no grant associated), time spent preparing grant applications, start-up packages for new faculty, and exploratory "departmental" research, university funds must be used to pay these expenses. When research is done off campus, or if it is non-laboratory based clinical research, the F&A rate does not include facilities fees, so the F&A rate is capped at the 26% administrative cost. Some training grants have an overall F&A limit of only 8%. Medical schools usually utilize their off-campus F&A rate (26%) for administration of NIH awards to VA researchers conducting research at the VAMC.

² "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards." OMB Guidance. 2 CFR Part 200.

As medical school faculty confront difficult decisions in sustaining labs, training programs, and other vital activities, they also need to consider the important role that direct and F&A payments play in the long-term sustainability of institutions. The funding institutions receive from NIH and other agencies does not fully cover the costs of research. On average medical schools spend an additional \$0.53 for every dollar of sponsored research received to cover the costs of unreimbursed F&A and other research expenses.³ As illustrated by this report, VA academic affiliates subsidize all research conducted on campus, including VA research. It should be noted that VA salary support of investigators (especially researchers who do not have clinical duties) is an important contribution to their overall support.

In 2003, the VA requested that NIH issue F&A cost reimbursement to the VA when some of the NIH-sponsored research was conducted in VA facilities.⁴ The NIH responded that “since 1982, the Department of Health and Human Services (DHHS) has had a policy in effect that prohibits payment of F&A costs to Federal institutions.” Additionally, the NIH noted that “VA’s infrastructure is supported through its own Federal appropriation.” VA infrastructure is supported by VERA which is calculated based in part on a weighted formula of reported research expenditures. The formula gives 100 percent credit for VA- or NPC-administered awards and a 75 percent credit for awards administered by the academic affiliate. The current year’s VERA Research Support allocations are calculated from the direct costs reported two years earlier.

In summary, F&A reimbursement is based on costs that are incurred for joint objectives and cannot be identified with a particular sponsored project. When an academic affiliate administers an NIH award for research conducted at the VAMC, the F&A rate is capped at 26%. An AAMC study indicates that F&A reimbursement does not fully cover costs, and institutions subsidize all research activities in addition to making other investments – buildings, research equipment, supporting research staff, information systems, bridge funding, among others. VA infrastructure is supported by VERA, and HHS has a policy in place that prohibits payment of NIH F&A to the VA.

4. The AAMC recommends that, when appropriate, academic affiliates administering NIH awards that utilize VA resources should subcontract with the NPC for VA services, and vice versa.

The report states:

“A majority of interviewees explained that when the affiliate manages the grant of a dual appointed VA investigator, and some or all of the work is performed at the VA, the NPC is awarded a subcontract/subaward to cover the costs of the work performed at VA. At roughly one-third of VAs/NPCs, interviewees noted that the affiliate, when acting as prime, does not

³ “Academic Medicine Investment in Medical Research.” 2015. <https://members.aamc.org/eweb/upload/academic%20medicine%20investment%20in%20medical%20research.pdf>

⁴ “Facilities and Administrative Costs on Grants to Academic Institutions for Research Conducted at Veteran Administration Sites.” 2003. https://grants.nih.gov/grants/policy/va_fa_costs.htm

always provide a subaward to the NPC even when work is conducted at the VA. At some NPCs that do not receive subawards from the affiliate for work conducted at the VA, the affiliate and the VAMC have an alternate arrangement to recapture costs associated with grant performance.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-45*

As indicated in the Westat study, “... at most locations, interviewees told us that under those circumstances, a subaward was common practice and happens more or less consistently.” Some institutions have other mechanisms to provide support for VA research which may involve support of staff, transfer of funds through other payments, or other arrangements.

5. The AAMC recommends that the VA ORD and NPCs educate VA researchers about resources and services offered by NPCs to increase their visibility.

The report states:

“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 for the VA.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-9*

The Westat report found that there was “insufficient NPC visibility and promotion.” Indeed, several of the interview responses in the Westat report indicated that VA investigators were unaware that their NPC exists. VA ORD and NPCs should increase engagement with VA investigators, including education on VA NPC capabilities and outreach to new employees.

6. The AAMC recommends that local academic affiliates, VAMCs, and NPCs discuss and reconcile potential investigator conflicts of commitments, if present, as research awards are administered. These potential conflicts of commitments should be reconciled so that interests of veterans are prioritized.

The report states:

“...dual appointed VA PIs feel considerable career pressure to submit their NIH grants—or sometimes all federal grants—through the academic affiliate. Several interviewees characterized this dynamic as a conflict of interest, since it may encourage decisions based on factors other than what is best for the VA or for Veterans. Others considered this dynamic a normal part of an academic career, in which faculty support the university’s goals by bringing grants to the university, and receive salary support for work performed above a 40-hour workweek, tenure, and promotion” *Study on Veterans Affairs (VA) Extramural Funding, page 3-12*

NPCs play an integral role in administering VA researcher awards, but NPCs may have limited or no experience in administering NIH awards. They may also not have the staff expertise or

other resources needed to complete these tasks. Therefore, it is not surprising that there may be preferences for dually-appointed VA PIs to submit federal grants through their academic affiliate, which has a robust infrastructure in place and a history of managing extramural awards, as well as resources and facilities often not available at the VAMCs. Westat sought a limited set of perspectives for the interviews regarding incentives and disincentives for NPC administration of NIH awards, and the perspectives of investigators and affiliate researchers and business officer administrators was not gathered.

As part of promotion and tenure process at the academic affiliate, a dossier of achievements is submitted for review by the investigator and their department. The information provided to the promotion and tenure committee identifies all research support irrespective of which entity administers the award. Therefore, administration of an award by the NPC versus the affiliate has no effect on faculty promotion and tenure. As part of an NIH award, salary support for investigators can be administered through the affiliate or NPC.

Researchers with joint appointments who apply for NIH funding utilizing VA resources must have a memorandum of understanding (MOU) signed by appropriate officials at the affiliate and the VA. The MOU describes responsibilities and the percent of effort available for research at each institution, and other professional responsibilities totaling to 100% of available effort.

If the affiliate administers the award, it is possible for investigators to report up to 40 hours per week at the VA and additional time at the affiliate institution. If the NIH grant is administered by the NPC, then the maximum time investigators can report is 40 hours per week.⁵ Recruitment of researchers is an important function for both the NPC and the affiliate. Affiliates usually provide the majority of support for recruitment and startup packages.

7. The AAMC recommends that VA increase the priority of the VA research enterprise and improve incentives for VAMC leadership to invest in research.

The report states:

“Some respondents pointed to a lack of financial incentives and others to a lack of career advancement incentives... A specific concern of interviewees raised numerous times pertained to the lack of protected research time for VA PIs. It was suggested that VA clinicians have no time to submit grant applications and conduct research.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-10 – 3-11*

As captured in the Westat report, an interview respondent recommended an “academization” of VA. AAMC recommends enhanced protected time for research, compensation for time worked over a 40-hour work week, performance metrics that reflect research activities, increased

⁵ “Manual for Administrative Officers and Associate Chiefs of Staff.” 2018.
https://www.research.va.gov/resources/policies/guidance/AO_ACOS_Manual.docx

investigator recruitment, additional VERA funding for research, and greater incentives for VAMC leadership to prioritize research.

8. The AAMC recommends that VA and NPCs allocate additional resources and staff (e.g., through Intergovernmental Personnel Agreements) to pre/post award grant administration.

The report states:

“Many interviewees believed their NPC’s small number of staff and lack of infrastructure for handling the submission and administration of federal grants was a barrier to the NPC fulfilling its potential. These interviewees explained that their NPC faced an uphill battle to grow and manage more grants unless they could hire more research coordinators, administrative staff or other specialists.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-7*

Several NPCs, such as [NCIRE](#) in San Francisco, have developed impressive fundraising efforts to help support VA research. These approaches should be utilized by other NPCs. For NPCs to successfully compete for administration of NIH awards, they should hire appropriate staff with experience in NIH pre- and post-award administration.

9. The AAMC recommends increased VA research funding and research infrastructure for the intramural research program.

The report states:

“Interviewees attributed the deficit of clinical researchers to a lack of incentives for clinical research within the VA system and inadequate supports to prospective researchers... A few interviewees pointed out that the VA’s central mission continues to be clinical with the research endeavor lagging far behind.” *Study on Veterans Affairs (VA) Extramural Funding, page 3-10*

The Friends of VA Medical Care and Health Research (FOVA) and the Independent Budget Veteran’s Service Organizations (IBVSOs) recommended an FY 2019 appropriation of \$823 million for the VA Medical and Prosthetic Research. Additionally, state-of-the-art research requires an investment not only in technology and equipment, but also in facilities. For decades, the VA construction and maintenance appropriations have failed to provide the resources VA needs to replace, maintain, or upgrade its aging research facilities. Consequently, many VA facilities have run out of adequate research space, or existing space is unable to meet current standards. FOVA believes designating funds to specific VA research facilities is the only way to break this stalemate. For capital infrastructure, renovations, and maintenance, FOVA and the IBVSOs recommend at least \$50 million for up to five major construction projects in VA research facilities and \$175 million in non-recurring maintenance and minor construction funding to address deficiencies.

Rachel B. Ramoni, D.M.D., Sc.D.
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The AAMC values VA ORD's commitment to improving the lives of veterans and all Americans through research, health care discovery, and innovation, and we appreciate the opportunity to submit feedback about Westat's report. We look forward to continuing our work with VA ORD to support VA research.

Sincerely,

A handwritten signature in blue ink, appearing to read "A. Ommaya".

Alexander Ommaya, DSc
Senior Director, Clinical and Translational Research and Policy