

MEMORANDUM

May 20, 2010

TO: NPC Executive Directors
NPC Board Chairs

FROM: Barbara West, Executive Director, on Behalf of the NAVREF Board of Directors

SUBJECT: NPC Compensation for Full Time VA Investigators

Enclosed is a copy of NAVREF correspondence sent to Chief Research and Development Officer Joel Kupersmith, MD. During each NPC's next board of directors meeting, the NAVREF board encourages the directors to use this letter to prompt consideration of NAVREF's recommendation in regard to NPC compensation for full time VA investigators and to establish a local position on this matter.

Background: For over a year, the NAVREF board of directors has considered advice given to NPCs and VA investigators in legal opinions similar to the one attached to the enclosed letter to Dr. Kupersmith. The board was concerned about Regional Counsel opinions that condone NPC pay while simultaneously citing the potential ethical peril to the investigator and the NPC as well as the consequences of missteps. Before reaching its conclusions, the NAVREF board engaged in extensive discussion and consulted with Office of General Counsel attorneys and a former VA human resource management expert. After considerable deliberation over an extended period, the board concluded that the likelihood of violating federal ethics statutes and regulations and exposing the NPC and investigator to criminal prosecution could be significant and problematic. Therefore we are conveying the recommendation below to NAVREF members.

Recommendation: The NAVREF board recommends that regardless of the source of funding for a project (federal or private), NPCs should not directly pay compensation to full time VA investigators for work on VA research even if it is clearly stated that the work is to be performed outside of VA duty hours. In spite of obtaining legal opinions stating NPCs "may" pay full time VA investigators for work on NPC-administered VA research, the NAVREF board encourages NPCs to respectfully decline to do so.

With funder approval, an NPC may reimburse VA for time spent on NPC-administered VA research up to a full time VA position (8/8). Alternatively, if reimbursement to VA is not feasible, an NPC may compensate a part time (less than 8/8) investigator directly up to the equivalent of a full time VA position. However, in the latter case, the NPC must ensure that there is no possibility of dual compensation or conflicts of interest.

Conclusion: The seriousness of this matter has prompted the NAVREF board to take the unprecedented step of sending this memo and the enclosure to the chair of each NPC board as well as each executive director. The NAVREF board hopes that it will stimulate discussion at the next NPC board meeting

If you would like to discuss this memo or the enclosed letter, please do not hesitate to contact me at 301-656-5005 or bwest@navref.org.

May 17, 2010

Joel Kupersmith, MD (12)
Chief Research and Development Officer
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Dr. Kupersmith:

I am writing on behalf of the board of directors of the National Association of Veterans' Research and Education Foundations (NAVREF) to document concerns about VA-affiliated nonprofit research and education corporations (NPCs) paying compensation directly to full time VA-salaried investigators for work performed on NPC-administered VA research studies. This has been a topic of extensive board discussion and consultation for over a year.

Several NPCs have shared with NAVREF various Office of General Counsel opinions issued in response to inquiries from NPCs contemplating compensating VA-salaried investigators and from investigators requesting NPC compensation (sample enclosed). After analyzing the facts of each request, these opinions conclude that the NPC "may" hire the investigator but simultaneously acknowledge the potential for violations of the federal criminal conflicts of interest statutes found at 18 USC §§208 and 209 and the federal Standards of Conduct. Such opinions appear to condone the additional NPC compensation. In the NAVREF board's view, this creates a false sense of security among the VA investigators and NPCs regarding the acceptability of this practice. In reality, investigators and NPCs that participate in such ethically problematic pay arrangements are at very real risk of incurring the civil penalties described at 18 USC §216 and/or facing criminal prosecution.

The fundamental problem appears to be that the OGC opinions do not fully consider that the work proposed for NPC pay is **VA research**. Also, they rely on whether the project title for the work to be done for additional compensation is different from the investigator's other VA project(s) rather than whether the subject of the project falls within the investigator's body of research and defined VA job description. For example, if a full time VA investigator's VA-compensated research involves study of a certain brain enzyme, the NAVREF board feels work on a project involving the same enzyme – even with a different project title and sponsor - is not sufficiently different to justify NPC compensation over and above a full time VA salary. Further, the employee's job may be classified based on his or her entire body of work and to provide additional compensation for work included in a VA job classification is problematic.

Moreover, performing the work for which the investigators propose earning the NPC pay would be impossible without the use of VA resources, including VA laboratories, equipment and subjects. How can it be appropriate to use such government resources to generate personal income beyond a full-time federal salary, particularly when such work so clearly falls within the scope of their government position as do "a)" through "h)" on the enclosed opinion? The board understands that VA employees may "moonlight." However, what is being proposed and apparently condoned in these OGC opinions appears to the NAVREF board to be very different

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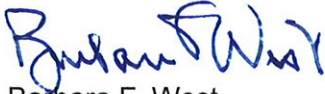
from, for example, providing 11:00 p.m. to 7:00 a.m. emergency room coverage at a nearby community hospital.

The complexity of managing these pay situations, with the associated prosecution risks to VA personnel and NPCs, compels the NAVREF board to recommend that NPCs should not directly pay full time VA-salaried investigators. However, with funder approval, NPC **reimbursement** to VA for effort on NPC-administered VA research projects is in the board's view appropriate. That arrangement puts VA and the investigator's VA supervisors in the position of managing the work, defining the employee's total compensation and overseeing the ethical considerations.

Please be aware that NAVREF plans to share a copy of this letter with the executive director and board chair of each NPC so that no site unwittingly runs afoul of the many regulations and related issues affecting the matter of NPC pay to VA investigators.

Please do not hesitate to contact me if you would like to discuss the NAVREF board's concerns or if you have questions. Clarifying policy would be helpful in assuring that no inappropriate actions are taken by NPCs or VA employees. Thank you for considering our views.

Sincerely,



Barbara F. West
Executive Director

cc: Holly Birdsall, MD, PhD
Kimberly Collins
Walter Hall
Renée Szybala

DEPARTMENT OF VETERANS AFFAIRS



In Reply Refer To: [REDACTED]
SMC

[REDACTED]

RE: [REDACTED]
Investigator, Staff Physician - [REDACTED]

1. You ask [REDACTED] can work for the [REDACTED] Research Institute ([REDACTED] RI) after hours. Dr. [REDACTED] has a tour of duty from 8:00am to 4:30pm. We understand that the clinical responsibilities will take precedence over [REDACTED] RI compensated work. It is understood that the physician investigator may be called upon to perform clinical duties outside of his/her normal tour of duty (i.e. "on call" duties and clinical responsibilities) that carry over after normal tour of duty when a physician investigator is not "on call". You further advise that the time proposed to work on the [REDACTED] VA approved research protocol will be on weekday afternoons, after the end [REDACTED] tour of duty, on weekends, and on annual leave time. We understand [REDACTED] will provide a bi-weekly accounting of a) specific times of [REDACTED] RI research related work, and b) specific tasks performed for [REDACTED] RI research related work. You state [REDACTED] will perform the following for [REDACTED] RI:

- a) Prepare research proposals for review and approval by the appropriate [REDACTED] VA research committees.
- b) Where appropriate, work in conjunction with co-investigators at the [REDACTED] School of Medicine Departments of Medicine and Family and Preventive Medicine; [REDACTED] School of Public Health; and [REDACTED] School of Nursing; as well as other institutions to carry out [REDACTED] VA research related activities.
- c) On his own and with the assistance of co-investigators and other research related personnel, [REDACTED] will analyze study data and refine the clinical research methodologies and questions.
- d) He will also gather the appropriate documents (references, patient data) and organize the data from the clinical research studies in preparation for and submission to peer-review and other publications.
- e) Meet with co investigators or teleconference with co investigators on a regular basis
- f) Prepare pertinent materials for presentation at local, national, and international meetings.
- g) The tasks performed for [REDACTED] RI compensation, will not relate to and are outside of the scope of [REDACTED] official duties as a full time [REDACTED] VA [REDACTED]...No clinical decisions or treatments, on any Veteran patients, will be made by [REDACTED], for [REDACTED] RI compensated research work, while [REDACTED] is paid as a [REDACTED] VA physician.
- h) The [REDACTED] RI compensated work will be related to renal epidemiology and not to clinical practice on individual patients,

2. [REDACTED], has signed a statement as supervisor to [REDACTED]. [REDACTED] states that [REDACTED] job performance is meeting the full responsibility of the role for which he has been hired and is compensated by the VA. [REDACTED] made this determination in consideration of outside employment for 'unrelated duties for the [REDACTED] Research Institute and with regard to [REDACTED] RI Policy Number 05-07.

3. First, decisions of whether to hire an employee rest with the nonprofit corporation, The NPC must determine if it is in the best interest of the NPC and in facilitating VA research to fund this person's salary and benefits. VHA Handbook 1200.17, para. 2, VA Research and Education Corporation Authorized by Title 38 USC §§ 7361 through 7368, December 17, 2001. Second, the medical center Director must decide whether to grant a Without Compensation (WOC) appointment. The Director must be made aware of the issues that surround such an appointment in this instance.

4. The VA employee hired by the NPC and given a WOC appointment to work as a researcher at VA must be careful not to violate the criminal conflict of interest laws and the Standards of Conduct. For this clinician, that means that he must not be paid by the NPC to perform his VA job (18 U.S.C. § 209). Under 18 U.S.C. §209 it is a federal crime for a government employee to receive compensation from an outside source for doing his official duties (i.e. dual compensation). While he is a full-time clinician, VA nevertheless encourages its employees to perform research. As a result, he has been involved in a great deal of research as part of his VA job. Therefore, any research that he is already doing as part of his VA job may not now be done as an NPC employee. This prohibition would affect any project he is working on, no matter what stage it is in.

5. The second applicable criminal prohibition is that the clinician may not participate through decision, recommendation or other action, in any particular matter that directly and predictably affects his financial interest -in this case, his NPC salary (18 U.S.C. § 208). In relevant part, the criminal conflict of interest statute, 18 U.S.C. § 208(a), prohibits

- an employee from participating personally and substantially (As PI with a WOC appointment)
- in an official capacity (as VA employee/PI with WOC appointment)
- in any particular matter (Decision making process of whether to do a particular Drug Study/CRADA)
- that will have a direct and predictable effect (financial gain)
- on the financial interests (payment to NPC and ultimately to PI)
- of any organization in which the individual serves as an officer, director, trustee, or employee. (PI is an employee of NPC)

6. This means that the clinician may not recommend or be part of the decision-making process as to whether or not VA accepts a particular study because his NPC salary would be derived from the money brought in by his research. Thus, his going before the R&D committee or IRB would not be allowed because he could not earn an NPC salary or other financial benefit arising from his recommendation, decision, approval or other action. He may perform research and other duties unrelated to the VA decision making process.

7. You, [REDACTED] RI, must understand the ramifications of this prohibition before you can knowingly decide if it is advisable to pay this employee's NPC salary. The medical center Director must also understand the limitations on the employee before giving a WOC appointment. Finally, [REDACTED] must understand the criminal prohibitions that face him.

8. In sum, [REDACTED] may work as a researcher for the NPC outside of his tour of duty and scope of practice. [REDACTED] RI and the VAMC are cautioned regarding 18 USC 208 implications. Based on said caution a decision must be made whether to hire [REDACTED] and give him a WOC appointment. Please feel free to contact [REDACTED] with any questions regarding this matter.

[REDACTED]
Regional Counsel