



DEPARTMENT OF VETERANS AFFAIRS  
Office of the General Counsel  
Washington DC 20420

SEP 30 1996

In Reply Refer To: 024M

• Ms. Barbara West  
Executive Director  
National Association of Veterans' Research  
and Education Foundations  
5018 Sangamore Road, Suite 300  
Bethesda, MD 20816

Dear Ms. West:

This is in response to your inquiry of March 15, 1996, requesting our legal opinion as to whether VA nonprofit research corporations (NPCs) may enter into Cooperative Research and Development Agreements (CRADAs) with VA Medical Centers. This correspondence was a result of a meeting you had with Dr. Richard Levine, in his capacity as Chairman, Institute for Clinical Research, Inc., Washington, DC, and Ms. Bea Pacheco of my staff.

As you know, NPCs were set up by Congress to provide a flexible funding mechanism for the conduct of approved research at VAMCs. 38 USC § 7361. The NPCs do not conduct research, and OGC opinions have held that NPCs are not "agents" for VA and thus may not agree to any terms or conditions that affect such research. An NPC appears to be limited, therefore, to administering funds it receives from outside entities in accordance with the approved research protocol.

Prior opinions have also held that NPCs may not enter into CRADAs *on behalf of* VAMCs. CRADAs are contracts and NPCs have no contractual authority to bind the agency, nor are they "Government operated laboratories" within the definition of the Federal Technology Transfer Act (FTTA). You indicated you were aware of, and in fact provided copies of, prior OGC opinions in this regard. However, you argue that the FTTA authorizes the VAMC to enter into a CRADA with the NPC and a third party.

The FTTA provides that each Federal agency may permit the director of any of its Government-operated laboratories to enter into CRADAs "with other Federal agencies...public and private foundations...nonprofit organizations, or other persons..." Thus, you are correct that broad authority

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exists under FTTA with regard to what entities VA may contract with for cooperative research.

However, we find no authority to justify a three-way agreement such as the one you have contemplated under FTTA. The subject of any CRADA is "cooperative research." It is unclear what an NPC would be bringing to a CRADA. The statutory language with regard to what may be defined as "cooperative research" is broad (for example, we have held that patient studies are "cooperative research" and properly the subject of CRADAs). As noted earlier, however, the NPC does not conduct research of any type. Clearly the FTTA contemplates a joint undertaking between parties who share a common interest and commitment to undertake a joint research endeavor.

As possible benefit to NPC involvement to a CRADA, you noted the NPC's ability to hire personnel not subject to FTEE restrictions to conduct the research. However, recent amendments to the FTTA (Pub. L. No. 104-113, March 7, 1996), now provide that the federal laboratory may hire personnel to conduct research under CRADAs without agency FTEE restrictions when funded through the CRADA agreement. 15 USC § 3710a(b)(3)(B).

We question the need for NPC involvement in any CRADA. The "flexible funding mechanism" that may be necessary for other types of research agreements is not necessary here because the FTTA gives authority for VAMCs to accept and administer funds under a CRADA. Additional potential benefits you noted were NPC administration of CRADAs and locating potential CRADA partners. While these may be matters that would be beneficial to the VAMCs, they do not reflect legal justification for an NPC to be a party to a CRADA. These are services that an NPC may perform without the necessity of being a party to a CRADA.

We hope the above is of assistance to you. If you have any further questions in this regard, Ms. Pacheco is available to assist you and may be reached at 202-273-6365.

Sincerely yours,



Neal C. Lawson  
Assistant General Counsel

# National Association of Veterans' Research and Education Foundations

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5018 Sangamore Road, Suite 300, Bethesda, MD 20816 Phone: 301-229-1048 FAX: 301-229-0442

Jeanette Evans-Hamilton  
Chairman

Barbara F. West  
Executive Director

## **Impact of VA Nonprofit Research Corporation Authorization Legislation Passed by Congress on Saturday, September 28, 1996**

1. **VA medical centers are authorized to establish new nonprofit research corporations.** Under this renewed authority, new corporations may be established until December 31, 2000. However, a newly established corporation still must be recognized by the IRS as a tax exempt nonprofit within three years of its date of establishment.

2. **Corporations are required to have an audit at least once every three years.**

A corporation with revenues in excess of \$300,000 for any year shall obtain an audit of the corporation for that year. A corporation with annual revenues between \$10,000 and \$300,000 shall obtain an independent audit of the corporation at least once every three years. Any audit under the preceding sentences shall be performed by an independent auditor. The corporation shall include the most recent such audit in the corporation's report to the Secretary for that year.

3. **Corporation employees are required to sign an ethics statement just once instead of annually, and the executive director will certify compliance instead of submitting copies with the annual reports.**

Paraphrased provision: Each corporation shall submit to the Secretary a statement signed by the executive director certifying that each director and employee is aware of, and has complied with, Federal laws and regulations pertaining to conflicts of interest in the same manner as Federal employees are required to.

To comply with this streamlined version of the existing requirement, at the time an employee is hired by the corporation, he/she should sign a statement certifying compliance with, and awareness of, Federal laws and regulations pertaining to conflicts of interest. This statement should be retained in the employee's personnel file. Once a year, the executive director should verify that each employee has signed such a statement, and should include in the annual report submitted to the Secretary a short statement certifying that every employee is in compliance.

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4. **The VA's annual report to Congress will contain additional information. As a result, the annual reports each corporation must submit to the Secretary each year on June 1 will be revised to reflect the new reporting requirements.**

To make sure that these new reporting requirements do not overburden the NPCs, NAVREF convinced key congressional staff to make the new requirements as consistent as possible with information that is readily available on the IRS Form 990 each corporation already is required to complete.

However, to comply with these requirements, each corporation must make sure that its Form 990 correctly identifies revenue sources and functional expenses. Corporations should make clear to their accountants that it is unacceptable to report only total functional expenses. The totals (Line 44) must be broken down into the categories provided on Form 990, Part II, Lines 22-43.

VA's annual report to Congress will contain the following [corresponding IRS Form 990 line items are identified in brackets following each requirement]:

- Location of each corporation [C]
- The amount received by each corporation during the previous year including—
  - total revenues [Form 990, Line 12]
  - the amount received from governmental entities [Form 990, Line 1c]
  - the amount received from all other sources [Total of Form 990 Lines 1a, 1b and 2]
  - information that identifies each donor whose total contributions for the year exceed \$25,000; provide name, address and total dollar amount
- The amount expended by each corporation during the year, including—
  - the amount expended for salary for research staff [Total of Form 990 Lines 25, 26, 27, 29, Column (B)]
  - the amount expended for salary for support staff [Total of Form 990 Lines 25, 26, 27, 29, Column (C)]
  - the amount expended for direct support of research [Form 990, Line 44, Column (B)]
  - information that identifies every payee—entities and individuals—that received payment in excess of \$35,000

Questions may be directed to the NAVREF office at 301-229-1048.

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