



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.

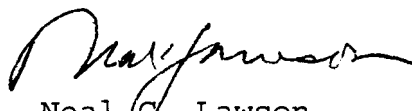
However, we find no authority to justify a three-way agreement such as the one you have contemplated under FTTA. The subject of any CRADA is "cooperative research." It is unclear what an NPC would be bringing to a CRADA. The statutory language with regard to what may be defined as "cooperative research" 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