



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

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Teresa L. Wright, MD
Chief, Gastroenterology Section 111B
VA Medical Center
4150 Clement Street
San Francisco, California 94121

In Reply Refer To: 023

1. At the request of the VA Chief of Patient Care Services, you asked our office to review a research proposal to be funded by a gift from the Schering-Plough Corporation.

2. In addition to the information you submitted, we have spoken with the Chief of Patient Care Services and with the Executive Director of the Northern California Institute for Research and Education (NCIRE). NCIRE is located at the San Francisco VA Medical Center and is an authorized and established VA research corporation pursuant to 38 U.S.C. § 7361 (the "corporation statute"). During these discussions, we learned that the proposal contemplates that NCIRE would administer funds for the research and that it would be a multi-center study conducted at VA Medical Centers across the country. The principal investigator would be based at the San Francisco VA Medical Center. We understand that the concern of the Chief of Patient Care Services is whether the multi-center aspect of the proposal renders it unlawful. Based on these discussions, the legal question presented is whether research that research corporations may lawfully support includes "multi-center" research.

3. The corporation statute conveys authority for corporations to be established "at any . . . medical center . . . to provide a flexible funding mechanism for the conduct of research at the medical center." 38 U.S.C. § 7361(a) (emphasis added). This implies that a corporation could lawfully support only those parts of a multi-center project which were being carried out at the specific medical center where the corporation had been established. However, VA manual provisions demonstrate that for at least two years before enactment of the corporation law in 1988, VA research was authorized to be conducted on a multi-

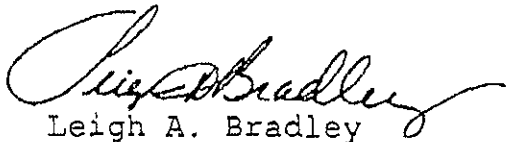
2.

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center basis. VA Manual M-3, Part I, ch. 1, para. 1.01f., 1.01l. (1985) (defining "cooperating investigator," "collaborating investigator," and "cooperative study" as involving more than one health care facility).

4. Moreover, we understand that most projects have one principal investigator and would typically, therefore, be managed from one medical center, i.e., the duty station of that investigator. In that sense, even a project being carried out at more than one medical center would constitute research "at a medical center." In our view, therefore, when Congress added funding flexibility for research "at any" or "at the" medical center, it did not intend to preclude flexibility for multi-center research being managed at the medical center that a corporation would be organized to support. From discussions regarding this proposal, our understanding is that it describes a project that could lawfully be supported by NCIRE, the corporation organized to support the San Francisco VA Medical Center.

5. Your letter mentions that in addition to NCIRE, the research corporation supporting the Miami VA Medical Center would be administering funds for the research called for in this proposal. In our view, the corporation law conveys sufficient flexibility to permit two research corporations to administer support for different portions of the same research. We do believe, however, that consistency with the purposes of the corporation law would require that the addition of the second corporation not be permitted to decrease the monies that are applied directly to the research. Thus, the amount of any administrative charges drawn off by both corporations would not properly exceed the customary amount that either corporation by itself would withhold in supporting a similar project.


Leigh A. Bradley

cc: Chief, Patient Care Services