

**Statement of  
Robert H. Roswell, M.D.  
Under Secretary for Health  
Department of Veterans Affairs  
on  
Non-profit Research Corporations and Educational Foundations  
and the Department of Veterans Affairs  
Human Studies Protection Program  
before the  
Subcommittee on Health and the Subcommittee on Oversight and Investigations of the  
Committee on Veterans' Affairs  
U.S. House of Representatives**

**May 16, 2002**

\*\*\*\*\*

Mr. Chairmen and Members of the Subcommittees:

Thank you for the opportunity to appear before you to discuss non-profit research corporations and educational foundations and the Department of Veterans Affairs (VA) Human Studies Protection Program.

**1. Non-profit Research Corporations and Educational Foundations  
Establishment**

In 1988, Congress authorized VA to establish non-profit research corporations at the medical center level "to provide a flexible funding mechanism for the conduct of approved research" (Title 38, Section 7361). Prior to this measure, VA medical centers had been limited to using the General Post Fund to accept and expend non-appropriated research funds. This new mechanism has helped VA research by increasing flexibility with respect to staffing and handling donated funds and grants. The Veterans Millennium Health Care and Benefits Act of 1999 expanded VA's authority by permitting the establishment of non-profit corporations to accept funds to facilitate research or education (or both). Education includes those activities supporting work-related instruction and training for VA-employed staff, as well as broad instructional and learning experiences directed toward improving and maintaining the health of the veteran patient. The Secretary of Veterans Affairs has delegated to medical center Directors the authority to establish corporations.

As of June 1, 2001, 88 research and/or education corporations had been chartered. Of these, 85 remain active. Recently, two facilities established education corporations that are separate from the research corporations already serving these facilities. The current practice of one research corporation per facility provides the optimum on-site service to investigators, immediate oversight by VA line officials, and helps comply with state and local requirements.

## **Recent Contributions**

In 2000, non-profit corporations received \$173.7 million in donations, grants, and interest for both research and education activities. This represents a 17% increase over the previous year and demonstrates that VA clinicians and basic scientists continue to be highly successful in competing for private and public sector research and education funding. Less than 1% of 2000 revenues were received in direct support of education.

Funding generated from private sector sources in 2000 totaled \$64.5 million and constituted the single largest source of donations. However, the number of corporations administering NIH grants has increased steadily since 1996, and NIH funding now represents the second largest source of all donations.

Non-profit corporations continued to manage funds very efficiently as evidenced by a low administrative overhead rate averaging 10 percent in contrast to the sector-wide average of 25 percent. As a result, 90 percent of all funds that corporations receive are available for the direct support of VA approved research and education.

In 2000, non-profit corporations supported 4,651 VA-approved projects, an eight percent increase over last year. Most of the projects are medical research clinical trials that focus on conditions prevalent in the veteran population and provide a direct benefit to VA patients. Non-profit corporations also provide salary support for clinical research personnel to monitor even more closely veteran patients enrolled in clinical trials.

Non-profit corporations benefit our veterans by generating funds that permit the acquisition of research equipment and supplies; space renovations; travel to scientific conferences; and salaries for research personnel including technicians, nurses, research coordinators, animal care takers, data clerks and investigators.

Specific examples of corporation support of VA medical centers include:

- a. Indianapolis VAMC: Received \$52,000 to purchase a confocal microscope and set aside \$87,000 to purchase equipment for a newly renovated wet laboratory that will include a new biosafety level 3 lab.
- b. Little Rock VAMC: VA investigators received funding for pilot studies, equipment purchases and bridge grants. Received three sets of animal cages at a cost of \$75,000 and salary funding salary for a full-time Research Compliance Officer and a half-time Safety Officer for a total cost of \$81,000.

## **Staffing**

By statute, the Board of Directors is responsible for the management and operation of the corporation. The board must consist of at least five members, including the statutory Directors, who are: the medical center Director, the Chief of Staff (COS), and the Associate Chief of Staff for Research (ACOS/R&D). The Associate Chief of Staff for Education (ACOS/E) is included for research and education corporations. At least two board members must be persons who are not officers or employees

of the Federal Government, and who are familiar with issues involving research or education and training as appropriate for the activities of the corporation.

The medical center Director is authorized to approve all appointments and all changes to the membership of the corporation's Board of Directors serving that VA medical center. The Board of Directors of each corporation has authority to act for the corporation as provided in its articles of incorporation and bylaws. This includes the authority to appoint, subject to the concurrence of the medical center Director, an Executive Director for the general operation of the corporation and to establish the specific duties and responsibilities of the Executive Director.

The corporation may employ individuals to work on VA-approved research projects or education and training activities. Corporation employees assigned to VA to provide research, education, or training services are subject to VA's supervision, direction, and control. All corporation employees, including VA employees who work for the corporation during their non-VA duty hours, who are assigned to VA to work on research projects or education and training activities, must have a Without Compensation (WOC) appointment regardless of whether they receive a corporate salary. All corporation board members, officers, and employees are subject to Federal statutes and regulations applicable to Federal employees with respect to conduct and conflicts of interest. VA employees who, as part of their official responsibilities have any role or function, whether statutory or otherwise, in the affairs or operations of corporations, are required to ensure that the corporations further the best interests of VA.

### **Management**

Ensuring the corporation's assets are used for research is the primary goal in the management of corporate funds. An appropriate official of the corporation must approve all expenditures. That official may be the Executive Director or another person designated by the corporation's Board of Directors. When transferring funds to VA, the corporation must document the transaction. The documentation may consist of the following: a bill for collection, an Intergovernmental Personnel Act (IPA) mobility assignment, or an approved Memorandum of Understanding (MOU), as well as other records.

The corporation must make and preserve records of the organization, including its functions, policies, decisions, procedures, and transactions in accordance with commonly accepted non-profit practices and commonly accepted accounting practices. These records must be: designed to furnish information needed to protect the legal and financial rights of the Federal Government and of persons directly affected by the corporation's activities; and maintained for the benefit of the corporation. All pertinent tax records for purposes of IRS review shall be retained for 6 years. All other non-tax records shall be retained according to Federal and state laws. The creation and maintenance of such records must be consistent with sound accounting principles

The corporations are engaged in business activities that generate tax-exempt revenues. They may not, consistent with their IRS tax-exempt status, engage in activities that would generate unrelated business income. Fundraising expenditures by the corporations are far below the national norms for nonprofits.

## **Oversight and Accountability**

Corporations, in connection with any audit, inquiry, investigation, or review of corporation activities, must cooperate with and make their records available to the VA Inspector General, the Comptroller General, the IRS, the Secretary of Veterans Affairs, and the State where the corporation is doing business. All corporations must submit a report each year to the Secretary of Veterans Affairs. Corporations with annual revenues between \$10,000 and \$300,000 must obtain an audit of the corporation at least every three years. Corporations with annual revenues over \$300,000 must obtain audits each year. The Executive Director of the corporation is responsible for providing a copy of the auditor's report to the Chief Fiscal Officer or equivalent at the VA medical center which the corporation serves.

By June 1 of each year, corporations must submit an annual report to either the Office of Research and Development (ORD) or the Office of Academic Affiliations in VA Central Office, or to both, as appropriate, detailing corporation funding and expenditures. Expenditures are reviewed for appropriateness by the corporation's Executive Director, board of directors, accountant, and auditor prior to incorporation in financial statements and the IRS Form 990, which is included in the annual report to VA. The annual report is required even if the corporation did not accept or expend funds during the previous year.

## **Conclusion**

Non-profit corporations are dedicated to fulfilling their congressional mandate in a responsible and conscientious manner, serving as a flexible funding mechanism for the conduct of VA-approved research and education. Revenues and expenditures in support of VA research and education programs are increasing, and the expertise of management is improving steadily as evidenced by corporation audit reports.

## **2. Protections for Human Participants in Research**

VHA's Research and Development program is focused upon the high priority health care needs of veterans. A special advantage of the VA research program is that it is nested within a health care system that serves more than six million enrolled veterans, creating a unique opportunity to discover and apply new medical knowledge. Most VA investigators are also clinicians who have responsibility for providing care for our patients and for training future health care providers for the nation. Unlike NIH, VA does not make research grants to colleges and universities, cities or states, or any other non-VA entity. Many advances in health care that benefit veterans and the nation have emerged from VA research – from the first treatments for tuberculosis and some of the first successful organ transplants, to the discovery of a gene for schizophrenia and improved treatments for Post-Traumatic Stress Disorder.

Given the importance of clinical research in VA, it is essential that our research program be committed to protecting the safety of patients and research subjects. VA is one of the 17 federal agencies that are signatories to the Common Rule for the Protection of Human Subjects of Research (38 CFR 16) and also has a separate regulation (38 CFR 17.85) that guarantees needed medical care for any

patient injured in a VA research project. All VA scientists are required to abide by stringent ethical principles and rigorous regulatory requirements to ensure the protection of people who participate in their research projects.

The protections offered to human subjects apply to all VA research regardless of sponsor or funding source. Much of the research conducted in VA facilities is also subject to the regulations of other federal agencies. For example, human studies funded by pharmaceutical companies and conducted at VA facilities in support of a new drug or device application are subject to FDA as well as VA regulations and oversight. Similarly, studies funded by NIH and conducted in VA facilities are subject to Department of Health and Human Services as well as VA regulations and oversight. Thus, the framework for a strong human subjects protection program has long been in place in VA.

During the past three years, VHA has taken a number of proactive steps to further enhance and strengthen protections for human subjects of research. In September 2000, the former Under Secretary for Health announced the establishment of the Office of Research Compliance and Assurance (ORCA). This office reports directly to the Under Secretary for Health and, under the direction of its Chief Officer, serves as primary advisor to the Under Secretary for Health on all matters affecting the integrity of VHA research as it relates to compliance and assurance. In addition to its oversight role, ORCA advocates and promotes the application of continuous quality improvement to enhance the ongoing protection of human subjects enrolled in research.

ORCA has launched the Training, Education, and Development (TED) Initiative, a program designed to develop and disseminate information on a wide spectrum of training and education activities, including those offered by public and private agencies, for investigators and research administrators. ORCA is currently developing a strategic plan for education and training for all VHA personnel involved in the protection of human subjects in research.

The Office of Research and Development (ORD) implemented a requirement that all VA investigators must provide documentation that they have participated in educational programs on human subjects protections before their research projects can be approved.

In the wake of VA's suspension of the research program at the Greater Los Angeles Health Care System and the closure of several research programs by other Federal oversight agencies, Dr. Kenneth Kizer, VA's former Under Secretary for Health, announced in his April 21, 1999, testimony before Congress that VA would become the driving force to establish both an accreditation entity and an accreditation process that will provide the public and our veterans the assurance that VA research programs meet or exceed established quality standards. The purpose of the accreditation program is to provide an independent, external validation that these research programs are functioning properly and effectively and to provide the necessary regulatory and ethical protections for research subjects. A notice was published requesting proposals for the establishment of such an accreditation program shortly after Dr. Kizer's announcement.

In April 2000, VA awarded a five-year contract for \$5.8 million dollars to the National Committee for Quality Assurance (NCQA), a private, non-profit accrediting organization dedicated to improving health care quality. NCQA has developed accreditation standards and will survey and determine the accreditation status of all VA facilities conducting human subjects research every three years. Accreditation site surveys began in September 2001.

In April 2001, the Institute of Medicine cited the standards NCQA developed for VA as the strongest basis for accreditation “because they pay specific attention to quality improvement, provide flexibility in achieving performance goals and are explicit in their grounding in current regulations.” NCQA’s accreditation standards cover six domains: Institutional Responsibilities, Institutional Review Board (IRB) Structure and Operations, Consideration of Risks and Benefits, Recruitment and Subject Selection, Privacy and Confidentiality and Informed Consent.

Since September 2001, 23 VA facilities have undergone NCQA accreditation surveys. As of May 8, 2002, eleven (11) final reports have been issued, with eight facilities being “Accredited with Conditions” and three facilities receiving a preliminary result of “Not Accredited.” The latter facilities are currently appealing the preliminary result before NCQA makes a final determination of their accreditation status. An additional 32 sites have been tentatively scheduled for accreditation surveys (with 14 confirmed to date) during fiscal year 2002.

The most common deficiencies involve three main areas:

- the lack of local facility policy and procedures related to IRB structure and operations,
- the lack of policy and procedures related to the Informed Consent process and the content of the informed consent document, and
- the evaluations and determinations the IRB must make and document during the initial review of research projects.

VA Central Office officials are currently assessing the situation to determine if any subjects have been placed at risk, and to implement any necessary safeguards. Once the final accreditation status is determined by NCQA, VACO and the facility will take appropriate corrective actions to ensure the protection of all subjects entered into research programs and compliance with all applicable regulations.

ORD has developed through the Cooperative Studies Program a Site Monitoring and Review Team (SMART). SMART consists of a Good Clinical Practice (GCP) Monitoring Group and a GCP Review Group established in 1998. The mission of SMART is to augment quality improvement activities in research. Reviews are performed at the study site and consist of reviewing the regulatory documents, the files of randomly selected patients and the informed consent process for all patients. The SMART program promotes GCP through four major service elements: (1) education, training, and certification for investigators and study coordinators, (2) site reviews to assess adherence to GCP and reinforce training, (3) GCP tools and guides for organizing files and activities, and (4) evaluation of consent forms.

We found that with these GCP review visits and our educational efforts, adherence to GCP improved significantly. The specific areas that improved were institutional review board interactions,

regulatory document management, patient records in investigator file, drug/device accountability, and general site operations. Based on the success of this program, ORD is establishing Accreditation Consulting Teams (ACT). ACT will use VA employees and consultants to help VA field facilities prepare for NCQA accreditation. Team members will be familiar with research, with VA and other federal regulations and policies for the protection of human participants in research, and with NCQA standards and survey procedures.

The Department of Veterans Affairs strives to lead the nation in assuring that its investigators follow the highest standards for assuring respect of the rights, dignity, and safety of research participants. We believe the approach VA is taking, with its continued emphasis on training and education, independent oversight and mandatory external accreditation will result in a system-wide human subjects protections program that will place VA at the forefront of ethical science.

Mr. Chairman, this concludes my statement concerning VA's non-profit corporations and the human studies protection program. My colleagues and I will now be happy to answer any questions that you and other members of the Subcommittees might have.