

Statement
of
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Department of Veterans Affairs
on
Human Research Participant Protection Program
before the
Subcommittee on Oversight and Investigations
of the
Committee on Veterans' Affairs
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Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to appear before you today to discuss the Department of Veterans Affairs (VA) human research participant protection program. We share your concern about research activities that placed patients at inappropriate risk or resulted in actual harm. The simple truth is that because of inappropriate research activities, some VA patients were placed in harm's way. It is unconscionable that any man or woman who wore a uniform in defense of our country be placed in jeopardy once again because they volunteered for research. We are in the process of changing our policies and operations in a manner that demonstrates that unethical research behaviors will not be tolerated. We will ensure that patients are optimally informed when they consent to participate in research, and that the research activities are safe and ethical. Thus, we have developed and are implementing new programs and training to support successful research conduct, management, and oversight at every level of the organization. Today, I would like to give you a progress report.

Since VA announced a research stand-down on March 6, 2003, we have made significant changes in the requirements for the conduct of research. First, we have required verification of appropriate Institutional Review Board (IRB) operation. In this process, leadership at each VA facility that conducts human research were required to certify that the local institutional review board (IRB) and research and development committee oversee human studies effectively. This process assures that research

protocols were adequately reviewed by an appropriately constituted IRB committee and that forceful provisions for ethical research conduct, such as good informed consent, are present.

Second, we have required training of over 15,000 individuals involved in human studies research in good clinical research practices. The good clinical practices program addresses the responsible, ethical, and accepted conduct of research. It provides particular focus on assuring the adequacy of informed consent and the increased responsibility for the care of patients in research protocols. Human studies research personnel are now also required to take refresher courses on an annual basis.

Third, to assure appropriate training and no history of illegal or unethical behavior, we have required credentials verification and background checks of VA research personnel with any degree patient contact or programmatic responsibility. Facilities were directed to confirm the credentials of all VA research personnel that come into contact with patients, not just those of independent health care providers. Sites are independently verifying education and professional certifications and have annual checks of all licenses. Facilities now repeatedly review the Department of Health and Human Services exclusionary lists to assure that they do not include any research staff. ORD is also creating an electronic means of tracking all employees involved in human subjects research to facilitate checking these individuals against exclusionary lists.

In the past 90 days, VA has achieved 98 percent compliance with the IRB verification requirements, 93 percent compliance with the training requirements, and 85 percent compliance with the credentialing responsibilities. As outliers have correction plans in place, we will achieve 100 percent compliance.

While VA demonstrated leadership in establishing an Office of Research Compliance and Assurance (ORCA) in 1999, our experiences have compelled us to establish mechanisms for more rapid, broad and effective development and dissemination of policy and education. These actions are directed to go beyond assurance of compliance and assure adequacy and integrity of research operations.

Recently, VA established the Program for Research Integrity Development and Education (PRIDE) within the Office of Research and Development (ORD). PRIDE is a

groundbreaking program that is responsible for all education, training, and policy development related to human research protection at the VA. Although it has been in existence for only a few weeks, PRIDE already has assisted in:

- Staffing the research “stand down”;
- Creating a blue ribbon advisory committee on ethical research conduct;
- Reinitiating the accreditation process for human research programs at VA facilities;
- Creating new programs for education and assistance;
- Establishing links with other organizations involved in the protection of human research subjects; and,
- During the three-month period of the research stand down, VA instituted credentialing standards for research personnel that exceed any in place anywhere in the United States.

VA has already sought, and is receiving, external guidance in setting the agenda for PRIDE. A nationally prominent panel to advise ORD and PRIDE on important issues pertaining to the protection of human subjects has been established. One of the foremost research ethicists (with particular expertise in informed consent), Dr. Baruch Brody from the Baylor College of Medicine, is heading the Blue Ribbon Panel on Maximizing Human Protection in VA Research. The panel includes members representing bioethics, health law, industry, and academia. The panel is charged with articulating the necessary structures and process for insuring ethical research. They are charged to base their work upon review of all relevant U.S. and international documents governing human subjects research.

PRIDE is already serving as a resource for providing guidance and policy development for responsible research conduct. These activities coordinate with, and require collaboration with, the policies and work of other agencies and organizations involved in protection of human subjects, both inside and outside the VA. Such entities include NCQA, the Food and Drug Administration, the National Institutes of Health, other components of VA, and quality assurance and patient safety organizations.

Policy development and education are only useful to the degree that they inform the actions of managers and researchers. One of PRIDE’s most critical initiatives is the

Center On Advice and Compliance Help or “COACH.” This new center is directed toward providing training and educational resources on all aspects of the ethics and the logistics of human research protection. COACH will communicate with local VA facilities and investigators in person, by phone, by e-mail, and will provide educational materials on the Internet and at local, regional and national meetings. COACH will also provide training in research conduct that will lead to successful research program accreditation.

In 2000, VA became the first Federal department or agency to seek independent, external accreditation of human research programs. Following a competitive selection process, VA contracted with the National Committee on Quality Assurance (NCQA) to develop and implement a comprehensive program. Based on a review of first-year evaluations, VA and NCQA placed this program on “pause” in the spring of 2002 to refine the logistics and better standardize the review criteria. Revised standards were published April 2003. The accreditation process will begin again this summer, and all VA facilities that have human research programs will complete the accreditation process by the summer of 2005.

While a new infrastructure has been developed in the ORD to support effective, rapid improvement in research conduct, VA believes strongly in independent oversight. As described, policy and programmatic educational activities now reside in the Office of Research and Development. Oversight of compliance with policy, regulation, law, and ethics is the responsibility of the Office of Research Oversight (ORO). All human resources of the predecessor office, ORCA, are contained in ORO and devoted to their charged responsibility for oversight of compliance with regulatory and policy aspects of human subjects protections, animal welfare, research safety, and research misconduct. ORO reports to the Office of the Under Secretary for Health.

Since its inception in 1999, ORO’s predecessor, ORCA, contributed in many ways to the improvement of VA’s protection of human subjects participating in research. ORCA provided prospective compliance consultations, retrospective compliance reviews, a compliance assurance program, and a training, education and development function.

Despite ORCA's remarkable contributions since 1999, continuing and intolerable breeches of human research conduct compelled us to make changes in office responsibilities. These changes modify, not abandon, the principles that brought ORCA forth. Oversight is required, but as Deming taught, quality cannot be inspected into a process. For improved outcomes, processes must be changed. As the Office of Research and Development has responsibility for the management of research processes, clear alignment of policy and training with ORD is critical. The diffusion of role responsibilities has unacceptably delayed necessary policy on human subjects protection. Moreover, reluctance of field managers and researchers to rapidly seek corrective assistance from the authority that imposes sanctions is understandable.

As all personnel in the former ORCA are now exclusively devoted to oversight in ORO, VA's capacity for research oversight is effectively increased. While we fully expect and are observing that ORO's investigations and reviews are educational, the Office of Research and Development's PRIDE and COACH programs have already established successful relationships with the responsible facility officials and researchers. Their early work, including training in good clinical research practices and policies requiring certification of IRP function and researcher credentialing, is proactively addressing and resolving potentially – and manifestly – problematic situations. As described, the progress in the past 90 days alone has been remarkable.

The legacy of ORCA's accomplishments will be used to facilitate the roles of both ORO and ORD in improving research. In addition to providing seminars for researchers and leadership, ORCA developed compliance information and tools for regulatory compliance, research program self-assessment, and continuous quality assurance. ORCA developed invaluable compendia of linked regulations, policy, and accreditation standards that were published on compact disk, a template for standard operating procedures in research compliance, and a web-based training program. ORCA also provided outreach to veterans about their rights in research.

Both ORO and ORD will benefit from ORCA's history of active participation at national meetings regarding ethical research conduct and regulatory initiatives. Both offices also benefit from established linkages with other Federal regulatory agencies and professional organizations such as the Office of Human Research Protections and

the Food and Drug Administration that help ensure consistent approaches to compliance oversight within VA, appropriate external reporting, and rapid correction of noncompliance.

ORD and ORO activities are increasingly complementary with oversight problems identified by ORO being met with aggressive solutions by ORD. It is also indisputable that ORO's oversight and investigative process is invariably educational. The skill set embodied by ORO staff in its five Regional Offices around the nation, and guided by ORO's Central Office component, is well capable of informed, consultative intervention.

ORO operations will continue in the tradition of ORCA which visited nearly all VA Medical Centers and Health Care Systems that conduct research and provided 10 formal prospective overview visits, 9 systematic post accreditation team visits to sites found not accredited by the National Committee for Quality Assurance, 19 major for-cause onsite reviews, 13 more limited visits to focus on issues of serious noncompliance in human subjects protections, and investigations of hundreds of compliance issues identified from sources within and outside of VA amenable to correction through compliance advice or action plans developed collaboratively with local facility personnel.

Because of its oversight mission, ORO will continue to serve as VA's governing body for Federal Wide Assurance (FWA) for VA facilities. ORO, in partnership with the Office of Human Research Protections in the Department of Health and Human Services, administers this assurance of compliance process, without which no IRB or human research program can operate.

Notably, ORO and its predecessor office negotiated over 100 Federal Wide Assurances and related agreements with VA facilities to assure their commitment to carrying out the Common Rule protections afforded to human subjects of research, and set forth in the VA regulations at 38 C.F.R. Part 16

While compliance is critical, ORD's now explicit responsibilities for policy, training, program management, and funding are linked in a manner that provides support for rapidly correcting deficiencies. Research programs that fail to appropriately safeguard patients and the values of ethical research conduct will have funding

terminated. In parallel, this transition affords ORO the opportunity to focus on oversight activities. In the past four years, ORO has laid extensive groundwork for a sound research oversight program to better assure compliance with policy, law, and ethical research conduct. Not surprisingly, ORO's increased oversight and assessment activities have resulted in increased numbers of findings and have revealed that ORO will need to continue its vigilance in the years and months ahead. As compliance issues are identified, the ORO compliance staff have worked closely with local facilities, research personnel, and the Veterans Integrated Service Networks to correct both isolated and systematic problems through prescribing and ensuring remedial actions.

In our revised program of protections, ORO will enjoy greater role clarity in discharging the oversight functions of its predecessor. The increased focus on oversight activities will assure that problems are investigated and – with ORD as a committed peer office, providing effective and timely policy and training – corrected. We commit to this so that the Department of Veterans Affairs maintains the highest quality research programs in the country, and most responsibly serves the needs of our nation's veterans.