

GAO

Testimony

Before the Subcommittee on Oversight  
and Investigations, Committee on  
Veterans' Affairs, House of  
Representatives

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VA RESEARCH

# Actions Insufficient to Further Strengthen Human Subject Protections

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Health and Benefits Issues





Highlights of [GAO-03-917T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

## Why GAO Did This Study

Every year thousands of veterans volunteer to participate in research projects under the auspices of the VA. Research offers the possibility of benefits to individual participants and to society, but it is not without risk to research subjects. VA studies, like other federally funded research programs, are governed by regulations designed to minimize risks and protect the rights and welfare of research participants. VA must ensure that veterans have accurate and understandable information so that they can make informed decisions about volunteering for research.

In September 2000, GAO reported on weaknesses it found in VA's systems for protecting human subjects. VA concurred with GAO's recommendations that its human subject protections could be strengthened by taking actions in five domains—guidance, training, monitoring and oversight, handling of adverse event reports, and funding of human subject protection activities. (*VA Research: Protections for Human Subjects Need to Be Strengthened*, [GAO/HEHS-00-155, Sept. 28, 2000]).

GAO was asked to assess whether VA has made sufficient progress in implementing the recommendations and to examine the recent changes in VA's organizational structure for monitoring and overseeing human subject protections.

[www.gao.gov/cgi-bin/getrpt?GAO-03-917T](http://www.gao.gov/cgi-bin/getrpt?GAO-03-917T).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Cynthia A. Bascetta at (202) 512-7101.

## VA RESEARCH

# Actions Insufficient to Further Strengthen Human Subject Protections

## What GAO Found

VA has not taken sufficient actions to strengthen its human subject protection systems since GAO made recommendations nearly 3 years ago. Continuing weaknesses VA has not sufficiently addressed include ensuring that

- its policy for implementing federal regulations for the protection of human subjects is up to date;
- training occurs periodically for all personnel involved in human subject protections;
- those charged with reviewing risks have information that can help them interpret reports of adverse events; and
- sufficient funding is allocated to support human subject protection activities.

VA has taken some important steps to strengthen aspects of its human subject protections by providing some necessary guidance and offering training to research personnel. Moreover, it strengthened its internal oversight and instituted an external accreditation program, with reviews of all its medical centers' human subject protection programs scheduled through summer 2005.

VA is now in the midst of a reorganization of its headquarters research offices that was begun without adequate planning and notice. VA did not initially ensure the independence of compliance activities although more recent actions appear to have restored the integrity of the compliance function. VA has not clarified responsibilities for education, training, and policy development. Until it does so, it is unclear how the reorganization will affect VA's efforts to further strengthen its human subject protections.

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here to discuss the protection of human subjects who participate in research conducted through the Department of Veterans Affairs (VA). Every year thousands of veterans volunteer to participate in research projects under the auspices of VA. Research offers the possibility of benefits to individual participants and to society, but it is not without risk to research subjects. VA studies, like other federally funded research programs, are governed by regulations designed to minimize risks and protect the rights and welfare of research participants. VA must ensure that veterans who agree to become subjects in VA research are given accurate and understandable information about procedures, risks, and benefits so that they can make informed decisions about volunteering. Concerns about VA's protection of its human research subjects came to national attention in March 1999. At that time, all human research was suspended at the West Los Angeles VA Medical Center after officials there failed to correct long-standing problems with its system for protecting human subjects.<sup>1</sup> Recently, serious concerns were raised about the safety of research programs at several VA medical centers, including the Albany VA medical center, where the possibility of patient deaths related to research is under investigation.

In September 2000, we testified before this subcommittee on weaknesses we found in VA's systems for protecting human subjects.<sup>2</sup> VA concurred with our recommendations to take immediate steps to ensure that human subjects would be protected in accordance with all applicable regulations. We made specific recommendations for actions in five domains—guidance, training, monitoring and oversight, handling of adverse event reports, and funding of human subject protection activities. You asked us to assess whether VA has made sufficient progress in implementing our recommendations and to examine the recent changes in VA's organizational structure for monitoring and overseeing human subject protections.

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<sup>1</sup>The West Los Angeles VA Medical Center is now part of the VA Greater Los Angeles Healthcare System.

<sup>2</sup>See U.S. General Accounting Office, *VA Research: System for Protecting Human Subjects Needs Improvements*, [GAO/T-HEHS-00-203](#) (Washington, D.C.: Sept. 28, 2000) and *VA Research: Protections for Human Subjects Need to Be Strengthened*, [GAO/HEHS-00-155](#) (Washington, D.C.: Sept. 28, 2000).

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My testimony is based on an update of VA's progress in implementing our September 2000 recommendations and a review of VA's recent and ongoing reorganization of its research offices. To do our work, we reviewed documents, including VA memorandums, policies, and guidance and interviewed key officials in VA headquarters. We conducted our work from May through June 2003 in accordance with generally accepted government auditing standards.

In summary, VA has not taken sufficient action to strengthen protections for human subjects, although it has made some progress. VA needs to address continuing weaknesses we identified nearly 3 years ago. Specifically, VA has not revised its policy for implementing federal regulations for the protection of human subjects. VA also has not established training requirements, in policy, to ensure that all research personnel will be informed of, and stay current with, ways to comply with all applicable regulations for the protection of human subjects. VA actions regarding two other recommendations are incomplete. VA has not ensured that those charged with reviewing risks related to ongoing research activities have information that can help them interpret reports of actual adverse events that research subjects experience while participating in studies. VA has also not ensured that sufficient funding is allocated to support human subject protection activities. On the other hand, VA has strengthened aspects of its human subject protections by providing some necessary guidance and offering training to research personnel. Moreover, it strengthened its internal oversight and instituted an external accreditation program, with reviews of all its medical centers' human subject protection programs scheduled through summer 2005.

In 2003, VA began a reorganization of its research offices without adequate planning and notice. We found that VA did not initially ensure the independence of compliance activities although more recent actions appear to have restored the integrity of the compliance function. In addition, VA has not clarified responsibilities for education, training, and policy development. Until these responsibilities are clarified, it is unclear how the reorganization will affect VA's progress in further responding to our recommendations to strengthen its human subject protections.

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## Background

Conducting research is one of VA's core missions.<sup>3</sup> VA researchers have been involved in a variety of important advances in medical research, including development of the cardiac pacemaker, kidney transplant technology, prosthetic devices, and drug treatments for high blood pressure and schizophrenia. In fiscal year 2002, VA supported studies by more than 3,000 scientists at 115 VA facilities. VA researchers receive additional grants and contracts from other federal agencies, such as the National Institutes of Health, research foundations, and private industry sponsors, including pharmaceutical companies.

To protect the rights and welfare of human research subjects, 17 federal departments and agencies, including VA, have adopted regulations designed to safeguard the rights of subjects and promote ethical research. These regulations, known as the Common Rule, establish minimum standards for the conduct and review of research to ensure that studies are conducted in accordance with certain basic ethical principles. These principles require that subjects voluntarily give their informed consent to participate in research, that the risks of research are reasonable in relation to the expected benefits to the individual or to society, and that procedures for selecting subjects are fair.<sup>4</sup>

The Common Rule creates a system in which the responsibility for protecting human subjects is assigned to three groups:

- Investigators are responsible for conducting research in accordance with regulations.
- Institutions are responsible for establishing oversight mechanisms for research, including committees known as institutional review boards (IRB), which are to review both research proposals and ongoing research to ensure that the rights and welfare of human subjects are protected. VA medical centers engaged in research involving human subjects may establish their own IRBs or secure the services of an IRB at an affiliated university or other VA medical center.
- Agencies, including VA, are responsible for ensuring that their IRBs comply with applicable federal regulations and have sufficient space and staff to accomplish their obligations.

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<sup>3</sup>VA's four core health care missions are patient care, education, research, and backup to the Department of Defense health system in war or other emergencies.

<sup>4</sup>38 C.F.R. pt. 16. VA regulations provide additional protections to those participating in human subjects research. See 38 C.F.R. §17.85.

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VA is responsible for ensuring that all human research it conducts or supports meets the requirements of VA regulations, regardless of whether that research is funded by VA, the research subjects are veterans, or the studies are conducted on VA grounds. In addition, two components of the Department of Health and Human Services (HHS) have oversight responsibilities for some VA research. The Food and Drug Administration (FDA) is responsible for protecting the rights of human subjects enrolled in research with products it regulates—drugs, medical devices, biologics, foods, and cosmetics. HHS-funded research is subject to oversight by its Office for Human Research Protections (OHRP). Both FDA and OHRP have the authority to monitor those studies conducted under their jurisdiction, and each can take action against investigators, IRBs, or institutions that fail to comply with applicable regulations. To facilitate assurance of compliance with federal regulations for the protection of human subjects, VA awarded a contract to the National Committee for Quality Assurance (NCQA) to provide external accreditation of its medical centers' human research protection programs in August 2000.

Two VA headquarters offices have responsibilities that are directly related to human subject protections. Responsibility for the administration of VA's research program rests with its Office of Research and Development (ORD), which allocates appropriated research funds to VA researchers. To help ensure that VA research is conducted ethically, legally, and safely, VA created an independent office to conduct compliance and oversight activities—the Office of Research Compliance and Assurance (ORCA)—in 1999. This office was given responsibilities for promoting and enhancing the ethical conduct of research and investigating allegations of research noncompliance; it reported directly to the Under Secretary for Health. In early 2003, VA reorganized its research offices and replaced ORCA with a new office, the Office of Research Oversight (ORO). ORCA's responsibilities for education, training, and policy guidance were transferred to ORD. ORCA's responsibilities for compliance activities were assigned to ORO.

In March 2003, ORD issued a memorandum announcing a 90-day national “stand down” for VA human subject research to be effective from March 10 through June 6, 2003, although research was permitted to continue during this period. The stand down was intended to focus efforts on identifying and correcting problems with VA's systems for protecting human subjects and to notify investigators that disciplinary actions may result from noncompliance with federal regulations governing the conduct of their research. ORD also asked medical center managers to attest that their IRBs are constituted as required by VA regulations and that they meet

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regularly enough to review research protocols and adverse events; that their research staff has obtained training in human subject protections; and that they have checked the credentials of all personnel involved in research, including investigators, research team members, IRB members and staff, and research and development committee members.

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### Earlier Evaluation Showed VA Needed to Strengthen Human Subject Protections

In 2000, we concluded that medical centers we visited did not comply with all regulations to protect the rights and welfare of research participants. Based on our review of eight medical centers, we documented an uneven, but disturbing, pattern of noncompliance with human subject protection regulations. The cumulative weight of the evidence indicated failures to consistently safeguard the rights and welfare of research subjects. Among the problems we observed were failures to provide adequate information to subjects before they participated in research, inadequate reviews of proposed and ongoing research, insufficient staff and space for IRBs, and incomplete documentation of IRB activities. We found relatively few problems at some sites that had stronger systems to protect human subjects, but we observed multiple problems at other sites. Although the results of our visits to medical centers could not be projected to VA as a whole, the extent of the problems we found strongly indicated that human subject protections at VA needed to be strengthened.

Although primary responsibility for implementation of human subject protections lies with medical centers, their IRBs, and investigators, we identified three specific systemwide weaknesses that compromised VA's ability to protect human subjects. First, VA headquarters had not provided medical center research staff with adequate guidance about human subject protections and thus had not ensured that research staff had all the information they needed to protect the rights and welfare of human subjects. Second, insufficient monitoring and oversight of local human subject protections by headquarters permitted noncompliance with regulations to go undetected and uncorrected. Third, VA had not ensured that funds needed for human subject protections were allocated for that purpose at medical centers, with officials at some medical centers reporting that they did not have sufficient resources for the staff, space, training, and equipment necessary to accomplish their mandated responsibilities.

To strengthen VA's protections of the rights and welfare of human subjects, we recommended that VA take immediate steps to ensure that VA medical centers, their IRBs, and VA investigators comply with all applicable regulations for the protection of human subjects. The specific

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actions we recommended involved guidance, training, monitoring and oversight, handling of information about adverse events, and funding of human subject protection activities. VA concurred with our recommendations.

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### **Insufficient Action Taken to Strengthen Protections for Human Subjects, Although VA Has Made Some Progress**

VA has not taken sufficient action to strengthen protections for human subjects since we made our recommendations nearly 3 years ago although it has taken some important steps. ORD has not revised its policy on human subject protections, and it has not established training requirements, in policy, to ensure that research personnel obtain periodic training. Moreover, VA has not established a mechanism for handling adverse event reports to ensure that IRBs have the information they need to safeguard the rights and welfare of human research participants and it has not ensured that sufficient resources are allocated to support human subject protection activities. On the other hand, VA has strengthened aspects of its human subject protection systems. ORCA developed a training program and conducted oversight activities by investigating claims of research improprieties or noncompliance and restricting or suspending four medical centers' research activities when it found evidence of serious problems. VA also instituted an external accreditation program that has the potential to further strengthen VA's oversight of human subject protections.

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### **Policy for Human Subject Protections Has Not Been Revised, but Other Important Guidance Was Issued**

In 2000, we reported that we had found problems with VA's policy for implementing federal regulations for the protection of human subjects. These problems included requirements for obtaining and documenting informed consent. For example, the policy requires use of a particular form to document a subject's consent to participate in research. This form calls for the signature of a witness, but does not indicate who may serve as a witness, to what the witness is attesting, or the circumstances under which a witness is needed.

In its comments to that report, VA indicated that ORD was in the process of updating its policy on human subject protections and that it expected to submit that policy for internal review by the end of August 2000. When we followed up in September 2001, VA reported that comments were being incorporated into the draft policy. In September 2002, VA reported that it was awaiting final review but has not issued its revised policy as of June 2003. As a result, investigators, IRB members and staff, and other research personnel do not yet have a clear, up-to-date policy to follow when implementing human subject protections. Consequently, VA cannot ensure

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that research staff know what they need to do to protect the rights and welfare of human research subjects.

In addition to the problems we noted with VA's policy, we reported in 2000 that VA headquarters had not provided medical center staff with adequate guidance to help them ensure the protection of human research subjects. VA has made some progress in this area. For example, ORCA had begun distributing some information to medical centers in early 2000. By January 2003, it had posted about 60 information letters and 14 alerts on its web page and through electronic mail to research facilities. These letters and alerts provide information about new HHS guidance and policies regarding human subject protections, reports on research ethics, and problems that ORCA staff observed during site visits to VA medical centers. In addition, ORCA developed guidance about human subject protections. For example, ORCA published a best practices guide for IRB procedures in September 2001 and a tool for medical centers to use to assess their human subject protection programs in October 2001.

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**Training Requirement Not Established in Policy, Although Training Opportunities Offered**

In 2000, we found that VA did not have a systemwide educational program focused on human subject protection issues. Although VA's human subject protection regulations do not include any specific educational requirements, we concluded that periodic training for investigators, IRB members, and IRB staff is necessary to ensure that they can meet their obligations to protect the rights and welfare of human research subjects.

VA has not established training requirements in policy, although on two occasions it has issued memorandums that required training. In August 2000, ORD issued a memorandum to medical center associate chiefs of staff for research stating that all VA investigators had to meet specific education requirements before submitting research proposals during 2001. ORD's memorandum regarding the March 2003 stand down stated that all research personnel must provide documentation that they have completed both a course on the protection of human research subjects and a course on good clinical practices within the past year; otherwise all research personnel must complete this training by June 6, 2003. These additional personnel include research coordinators and research assistants involved in human research; all members of VA research offices, research and development committees, and IRBs; and IRB staff (except secretarial staff). According to VA's policy for distributing information, however, memorandums are not used to establish permanent requirements or policy, and education and training requirements for investigators were not published in a directive or handbook, which are the documents VA uses to

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communicate policy requirements. As a result, headquarters cannot systematically ensure that all VA personnel involved in human subject research will be informed of, and stay current with, ways to comply with all applicable regulations for the protection of human subjects.

Despite the lack of policies requiring human subject protections training, both ORD and ORCA have provided information since we made our recommendation about available educational programs to investigators and other research personnel. ORCA worked with academic institutions to develop an optional training program for use by VA investigators, IRB members, IRB staff, research administrative staff, and medical center officials. This web-based training program includes quizzes after each module; certification of successful completion requires achieving a score of at least 75 percent correct. ORCA also presented a seminar on research compliance and assurance to senior managers of each of VA's networks,<sup>5</sup> and ORD recently began providing training to senior managers about their responsibilities regarding human subject protections.

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## Internal and External Oversight Strengthened

In 2000, we reported that VA had not identified widespread weaknesses in its human subject protection systems because of its low level of monitoring. VA has made progress in strengthening its oversight. ORCA, which was created in 1999, was charged with advising the Under Secretary for Health on all matters related to human subject protections, promoting the ethical conduct of research, and conducting prospective reviews and "for cause" investigations. Since becoming operational, ORCA has investigated claims of improper conduct of research and noncompliance. In about a dozen cases, it sent teams to medical centers to conduct intensive for cause reviews. ORCA also conducted six on-site reviews to follow up on findings from external accreditation reviews. As a result of its investigations, ORCA restricted or suspended research at four VA medical centers until identified problems were corrected. For example, in March 2001, ORCA restricted one medical center's human research activities by suspending enrollment of new subjects in research after its investigation revealed noncompliance with several regulations pertaining to IRBs.<sup>6</sup>

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<sup>5</sup>VA has 21 Veterans Integrated Service Networks that coordinate the activities of, and allocate funds to, VA medical centers, nursing homes, and other facilities in each region.

<sup>6</sup>The IRB of this medical center served as the IRB-of-record for a second VA medical center. Therefore, human research at two medical centers was affected.

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ORCA lifted this restriction in February 2002 after the medical center corrected the identified problems.

In addition to its internal oversight mechanisms, VA became the first research organization to arrange for external accreditation of human subject protection systems. External accreditation has the potential to significantly strengthen oversight of human subject protections. In August 2000, VA awarded a \$5.8 million, 5-year contract to NCQA to operate an accreditation program to assess medical centers' compliance with federal regulations for the protection of human subjects. VA's contract with NCQA requires it to develop accreditation standards, to conduct a site visit every 3 years to each VA medical center conducting human research, and to decide on the accreditation status of each facility. According to a 2001 report by the Institute of Medicine, the accreditation standards developed by NCQA provide a promising basis for accreditation because they are explicitly linked to federal regulations and pay attention to quality improvement.<sup>7</sup> The Institute of Medicine recommended that the NCQA standards be strengthened, for example, by specifying how research subjects will be involved in human subject protection systems.

NCQA began accrediting VA medical centers and has revised its accreditation process. NCQA conducted accreditation visits to 23 VA facilities from September 2001 through May 2002. An ORD official told us that, of those 23 facilities, 20 were accredited with conditions, 2 were not accredited, and 1 withdrew from the process. A facility accredited with conditions met most of the accreditation standards. On the basis of its experience and feedback on its standards, NCQA proposed—and ORD approved—revising the standards. NCQA discontinued accreditation reviews while it revised its standards for evaluating human subject protection programs. Revisions involved clarification of standards, reduction of redundancies, and changes to the scoring system. Some revisions were designed to respond to comments from the Institute of Medicine. For example, NCQA adopted standards to encourage a facility to obtain input from research subjects to improve its human subject protection system. ORD approved a new set of standards in April 2003. Site visits are expected to resume in October 2003, with accreditation reviews of all VA facilities involved in human subject research planned for completion by summer 2005.

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<sup>7</sup>Institute of Medicine, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs* (Washington, D.C.: National Academy Press, 2001).

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## Actions Regarding Adverse Event Reports and Funding for Human Subject Protection Activities Are Incomplete

In 2000, we reported that IRBs have difficulty handling adverse event reports and often lack key information necessary for their interpretation. Since then, VA has not developed a mechanism for handling adverse event reports to ensure that IRBs have information that can help them interpret reports of actual adverse events that research subjects experience while participating in studies. Federal regulations require investigators to report to the IRB unanticipated problems involving risks to subjects. In turn, IRBs are to review these adverse event reports as part of their continuing assessment of the adequacy of a study's protections for human subjects. ORD issued guidance stating that analyses of adverse events should be provided to IRBs for those clinical trials that VA funds at multiple medical centers. ORCA staff participated in interagency discussions about how to help IRBs handle adverse event reports and developed guidance regarding what adverse events IRBs are to report to ORCA. As of June 2003, this guidance has not been issued and VA still lacks comprehensive guidance to help IRBs interpret reports of adverse events.

In 2000, we reported that VA did not know what level of funding was necessary to support human subject protection activities and research officials at five of eight medical centers we visited told us that they had insufficient funds to ensure adequate operation of their human subject protection systems. In May 2000, ORD provided networks with suggestions for the level of administrative staffing of IRBs. ORD also commissioned a study of the costs of operating IRBs within VA, which was completed in June 2002. On June 13, 2003, VA issued a policy regarding funding for human subject protection programs that medical centers are to obtain from external sponsors of VA research. Specifically, the sponsor of each industry-funded study is to be charged 10 percent of the direct costs of the study or a flat fee of \$1,200, whichever is greater, by the medical center to help cover the costs of the human subject protection program. We have not had the opportunity to study the potential for this mechanism to help ensure sufficient funding. VA has not specified a procedure for ensuring that its medical centers—which conduct VA-funded research and research funded by federal agencies and research foundations as well as industries—will be allocated the funds necessary for their human subject protection programs.

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## Recent Reorganization Appears to Maintain Independent Compliance Function, but Other Roles and Responsibilities Unclear

In 2003, VA began a reorganization of its research offices without adequate planning and notice. We found that VA did not initially ensure the independence of compliance activities, although more recent actions appear to have restored the integrity of the compliance function. In addition, VA has not clarified responsibilities for education, training, and policy development.

VA's initial action to reorganize its research offices failed to ensure the independence of compliance activities. In January 2003, officials announced that the existing compliance office, ORCA, would be disbanded and the compliance function and staff reassigned to ORD. As a result, compliance field personnel began reporting their activities to ORD, potentially compromising the independence of their compliance investigations. In a series of memorandums issued from March through May of 2003, VA announced that a new office, ORO, would replace ORCA. VA memorandums indicated that ORO, like ORCA, would be independent of ORD, and that ORO would be organizationally responsible to the Under Secretary for Health.

According to generally accepted government auditing standards, offices with responsibility for assessing regulatory compliance should be organizationally independent of the offices they review and should report to, and be accountable to, the head or deputy head of the government entity.<sup>8</sup> Because VA considered making ORD responsible for compliance activities—where its independence would be compromised—legislation was proposed in the House of Representatives to establish an independent office within VA to oversee research compliance with federal regulations.<sup>9</sup>

According to VA memorandums and discussions with agency officials, ORO will have responsibility for investigating allegations of research noncompliance, misconduct, and improprieties. However, it is not clear whether ORO will have authority to review a medical center's human subject protection program in the absence of a prior allegation of a problem; that is, whether it can conduct prospective investigations. While

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<sup>8</sup>HHS separated its compliance office from its administrative office after we voiced similar concerns about independence. As a result, instead of reporting to the National Institutes of Health, which conducts and funds research, OHRP has been reporting to HHS's Assistant Secretary for Health since June 2000. See U.S. General Accounting Office, *Scientific Research: Continued Vigilance Critical to Protecting Human Subjects*, [GAO/HEHS-96-72](#) (Washington, D.C.: Mar. 8, 1996).

<sup>9</sup>H.R. 1585, 108th Cong. (2003).

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VA memorandums indicate that ORO will have the same compliance responsibilities that ORCA had and specify that for cause inspections will be conducted; they are silent on routine inspections. Experts in human subject protections have said that these routine inspections, sometimes referred to as prospective inspections, are an essential way to help prevent noncompliance. As of June 2003, a directive to formalize the authorities and responsibilities of ORO has not been issued. Consequently, ORO's compliance responsibilities remain unclear.

Other roles and responsibilities are also unclear. For example, ORCA previously had responsibilities for education and training. VA's reorganization now assigns these responsibilities solely to ORD. The implications of this transfer of responsibilities for strengthening human subject protections are unclear. For example, when ORCA conducted compliance reviews or followed up on results of accreditation reviews, it provided instruction about what steps would be necessary to correct identified problems. It is not clear whether or to what extent such instruction, including technical assistance regarding a specific area of noncompliance, would be considered to be education and training and therefore not within ORO's responsibilities.

ORCA also had responsibility to participate in the development of policies involving human subject protections. Under the reorganization, ORD would have responsibility for policy development. Existing memorandums are silent on whether ORO will have any role in, or can contribute its expertise to, policy development. ORCA had been created with the understanding that it would collaborate with ORD on dissemination of information, communication, and policy development. It is not clear to what extent VA's efforts to strengthen its human subject protections will bring to bear the collective expertise of the staff in its compliance and operational research offices. However, having ORD take the lead on policies regarding compliance functions or activities could be inappropriate to the extent that it interferes with ORO's independence in executing its compliance functions.

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Mr. Chairman, this concludes my prepared remarks. I will be pleased to answer any questions you or other members of the subcommittee may have.

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## Contact and Acknowledgments

For further information regarding this testimony, please contact Cynthia A. Bascetta at (202) 512-7101. Kristen Joan Anderson, Jacquelyn Clinton, Pamela Dooley, Lesia Mandzia, Marcia Mann, and Daniel Montinez also contributed to this statement.

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# Related GAO Products

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*Human Subjects Research: HHS Takes Steps to Strengthen Protections, but Concerns Remain.* [GAO-01-775T](#). Washington, D.C.: May 23, 2001.

*VA Research: Protections for Human Subjects Need to Be Strengthened.* [GAO/HEHS-00-155](#). Washington, D.C.: September 28, 2000.

*VA Research: System for Protecting Human Subjects Needs Improvements.* [GAO/T-HEHS-00-203](#). Washington, D.C.: September 28, 2000.

*Scientific Research: Continued Vigilance Critical to Protecting Human Subjects.* [GAO/T-HEHS-96-102](#). Washington, D.C.: March 12, 1996.

*Scientific Research: Continued Vigilance Critical to Protecting Human Subjects.* [GAO/HEHS-96-72](#). Washington, D.C.: March 8, 1996.

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