



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.