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## AUDIT LEADS TO ENROLLMENT HALT IN RESEARCH AT VETERANS HOSPITAL

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The veterans hospital in Seattle has halted all new enrollments in research involving human subjects after a federal audit found that patient safeguards weren't properly documented.

The decision — which applies to about 600 studies being conducted at the veterans hospital and the University of Washington — could delay the work of some researchers by weeks or longer, in some cases forcing them to turn to minor but still research-related tasks to avoid running afoul of the conditions of their research grants.

Researchers also will be barred from analyzing or publishing their data at the veterans hospital without a special waiver.

Also affected are about 15 bone-marrow transplant and oncology studies at the Fred Hutchinson Cancer Research Center that were actively recruiting patients at the hospital.

Nationally, the federal Department of Veterans Affairs has been a fertile proving ground for medical breakthroughs, including advances in artificial limbs, the CT scanner and drug trials for tuberculosis and hypertension.

Locally, thousands of veterans and their dependents are enrolled in human studies. The research spans a range of conditions and treatments, including testing the effects of testosterone in men with mild cognitive impairments to studying the genetic propensity for certain diseases.

Subjects often receive modest payment, ranging from \$20 or \$30 for a visit to \$200 for a lumbar puncture.

The restrictions in Seattle announced this week stem from a review completed last month by the federal department's Office of Research Oversight, which is responsible for ensuring patient safeguards.

The oversight office found, among other things, that patient-consent forms did not conform to department regulations and that local committees in charge of approving each clinical study failed to make a formal judgment about risk levels.

Dr. Steven Kahn, director of research and development at the VA Puget Sound Health Care System, which includes the hospital, stressed that the federal audit largely found record-keeping problems and raised no concerns with specific studies.

Kahn said that while this is the first time the hospital here has suspended enrollment in human studies, "there has been no violation of federal regulation and no harm to patients."

Kahn, who also is a professor of medicine at UW, said several other VA health systems — including Boise, San Diego and Palo Alto, Calif. — also have received similar findings from the federal oversight office.

Kahn said researchers can continue collecting data, blood and other samples from people already enrolled in their studies. However, they can't add new subjects or analyze or publish the results of their research until their study protocols have been re-reviewed and cleared.

Researchers can seek special waivers, Kahn said, if the delays would compromise patient safety or otherwise jeopardize their research.

Vera Sharav, president of Alliance for Human Research Protection, a New York nonprofit group that promotes ethical medical research, said particular care is needed to safeguard veterans enrolled in studies.

They "are vulnerable to being coerced into becoming guinea pigs in order to get treatment," she said.

Kahn said the action was unrelated to recent national headlines about patient-safety issues at VA research centers elsewhere around the country.

In August, a report by the department's inspector general's office concluded that VA researchers in central Arkansas broke rules on human experimentation multiple times since the 1980s.

Researchers allowed people with no medical experience to collect muscle tissue, destroyed consent forms and failed to report the deaths of 105 patients who had been involved in studies at VA facilities throughout Arkansas.

Later that month, Veterans Affairs Secretary James Peake apologized publicly to the widow of a veteran who died of a human form of mad-cow disease after being turned away from a veterans hospital in the Bronx borough in New York.

The man's family contended he was steered into hospice care after declining to enroll in an Alzheimer's study.

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