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Duke's Response

U.S. Halts Human Research at Duke

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The U.S. government has temporarily shut down federally funded research on humans at Duke University Medical Center, one of the nation's largest and most prestigious medical research facilities, after federal investigators determined that the university could not ensure the safety of participants.

The suspension of Duke's federal license to conduct human research is only the fourth such move by the government in nearly a decade and appears to be the largest yet in terms of the number of studies and people affected and the amount of money at stake. The Durham, N.C., center receives about $175 million a year from the federal government for medical research, officials said.

Among the problems cited by the government in its May 10 suspension letter to Duke was an oversight committee's failure to keep track of human studies after they began ï the only way to make sure people are not being unexpectedly harmed by research ï and a failure to document that special, federally mandated protections for children were in place.

Duke officials emphasized yesterday that there is no evidence anyone was harmed by the oversight lapses, which they characterized as largely "administrative" failings, such as poor recordkeeping. They expressed their support for research protections and said they hoped the issues could be cleared up quickly.

"Protection of human subjects in clinical trials is very serious business, and we're absolutely going to make certain that anyone in a research protocol is going to be fully protected," said Ralph Snyderman, Duke's chancellor for health affairs.

Snyderman noted that the government is allowing the continuation of certain therapeutic research studies whose sudden suspension might harm patients. But no new participants will be enrolled in those studies until federal investigators are satisfied that proper protections are in place.

The disciplinary action against Duke, by the federal Office for Protection from Research Risks (OPRR), follows a similar action by that agency against the Los Angeles Veterans Administration Hospital in March and reflects growing concern among government officials and advocacy groups that federal protections for human research subjects are inadequate or poorly enforced.

Last June, for example, the inspector general of the Department of Health and Human Services released a report that warned of an imminent breakdown in the nation's system for overseeing the safety of human research subjects. And the presidentially appointed National Bioethics Advisory Commission recently recommended sweeping new protections for mentally ill patients who participate in research studies.

The move against Duke also comes at a time when the OPRR, a small agency with the enormous responsibility of overseeing the safety of all federally funded human research, is struggling to respond to recent congressional criticism of the slow pace of some of its investigations.

The OPRR's investigation of Duke began with a visit to the medical campus last December. Unlike the vast majority of that agency's investigations, which are prompted by complaints from research participants or whistle-blowers, this was a random site visit, said OPRR director Gary Ellis ï one of very few ever conducted by the agency.

During that visit and subsequent interviews and exchanges of letters, the agency documented a long list of failings, most of them relating to the center's Institutional Review Board (IRB). The board reviews all proposed human research to ensure it is scientifically and ethically appropriate and passes muster with federal regulations.

Investigators found that the IRB was not keeping adequate written documentation, as required by law, describing how it decided to allow various studies to go forward.

They also found evidence that one member of the board ï Duke's director of grants and contracts, who has an interest in seeing Duke thrive as a recipient of research grants ï continued to vote on research proposals as an IRB member despite the OPRR's warning that his participation could be construed as a conflict of interest.

Investigators also found discrepancies between the number of IRB members recorded as present at meetings and the number of votes on research projects, raising questions about whether a quorum was present as required by law. They also determined that Duke's IRB did

not properly document whether some studies might have been allowed to go forward with fewer patient protections than are normally required.

After four months of discussions led, in the OPRR's opinion, to inadequate changes at Duke, the agency decided to make its move.

"When OPRR identified serious deficiencies in protecting human subjects in December 1998 at Duke University Medical Center, we believed that the university would move quickly to remedy them," Ellis said. "It was disappointing to see a protracted and unsatisfactory response." Ellis characterized Duke's failure to correct its problems in the past four months as a "failure of leadership."

Others, however, said they suspected that the OPRR's action was also motivated in part by a need to prove its mettle to Congress in the wake of recent allegations by patient groups and others that the government is failing to protect research subjects.

Historically, it has not been unusual for the OPRR to exchange letters with research centers for three to five years until problems are resolved, said Vera Sharav, head of Citizens for Responsible Care and Research, a New York City-based advocacy group.

Nonetheless, if the OPRR's vigor is representative of a new, more aggressive attitude by the agency ï including cracking down on bureaucratic lapses as well as on frank abuses of patients ï then citizens can only benefit, Sharav said.

"If no one does anything," she said, "then the violations get greater."

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