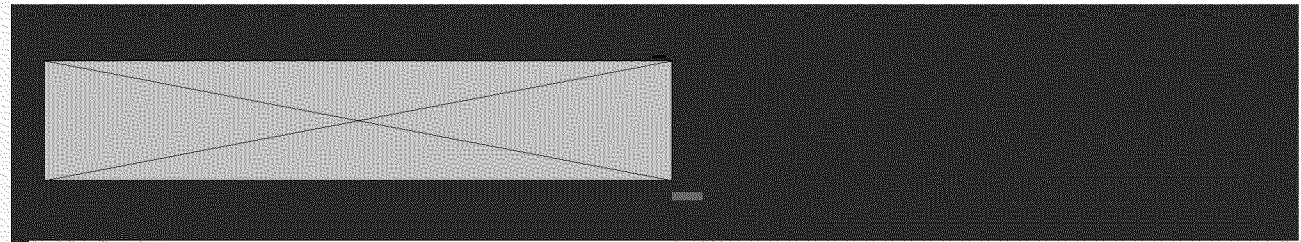


To: Jackson, Ryan[jackson.ryan@epa.gov]
From: The Washington Post
Sent: Mon 9/25/2017 4:01:36 PM
Subject: Federal Insider: Whistleblowers at U.S. funded research institutions fear retaliation



Whistleblowers at U.S. funded research institutions fear retaliation

By Joe Davidson

The Department of Health and Human Services (HHS) building in Washington. A report by the HHS inspector general's office says "fear of reprisals may prevent potential complainants from reporting suspected" violations of "protections for human subjects" in research projects. (Alex Brandon/Associated Press)

Institutions that conduct human research generally have a reputation for strict fact-finding, going where the research leads while maintaining firm rules to protect the people who are studied.

If those rules are violated, the consequences can be serious. It's worse when workers and others are afraid to report violations.

When a study does not follow procedures, patient safety is jeopardized, public confidence in the research institution and the government agency funding the work suffers, sometimes for decades, with the mistrust passing through generations.

Consider the impact of the Public Health Service's scandalous "Tuskegee Study of Untreated Syphilis in the Negro Male." Patients were denied needed treatment in the name of science. Launched in 1932, it lasted 40 years and is an example of perverted research with lingering negative consequences.

Now comes an investigative report about deterrents in reporting problems with human research. The Department of Health and Human Services (HHS)

Office of Inspector General found evidence of a fear of retaliation among whistleblowers in research institutions.

The human studies are funded by the federal government, but generally done by non-federal institutions, such as universities and hospitals.

The Department's Office for Human Research Protections (OHRP) does not provide adequate information on whistleblower protections for research employees and others, according to the report. That's a problem because "fear of reprisals may prevent potential complainants from reporting suspected" violations of "protections for human subjects" in research projects, the report said.

Whistleblowers have been transferred or put in fear of losing benefits.

"Information from whistleblowers is important because it can be insider information," said Joyce Greenleaf, a regional inspector general. "It can bring to light problems with critical research that puts volunteering human subjects at risk. So, to sustain the public's confidence in this research, we need people to be willing to bring these concerns to light."

Pressed for instances, the inspector general's office offered four cases that were not included in the report:

- A nurse who assisted with neurosurgeries at a medical center told investigators a surgeon delayed operations on patients for weeks to obtain equipment needed for a research study, but not needed to treat patients. "Nurse believes this is not in the best interest of the patients. Other nurses have voiced concerns but were reassigned."
- An ophthalmology resident in a large hospital said children and adults were enrolled in research that does not have appropriate approvals. Research involves chemotherapy to treat retinoblastoma, a cancer that begins in the retina, the black part of the eyeball. "There have been adverse events. Many research participants do not speak English, informed consent is inadequate and consent forms are not provided in the participant's native language." The whistleblower was "not comfortable complaining and does not want retaliation."
- A student athlete on a university scholarship "alleges that students do not have a choice but to participate in athletic testing research. The coach is in the room during the informed consent process, and the student alleges

Don't let the research that is being conducted by the Federal Reserve (with the recommendation that it be interesting in order to be able to provide that information) be used to protect the agency's interests. The agency's interests are not like refusing to participate may result in poor grades as well as a loss of scholarship." The student feels a need "to be cautious because this could affect his situation and career." help HHS determine whether it should seek legislative provisions, several examples of noncompliance particularly with cancer research trials, such as research not reviewed by the IRB, Meanwhile, the industry has not been able to get its submissions subject to the reporting requirements. And they need to be upheld, and we need to know that individuals working in these environments are reporting something that is important to the public. The report also notes that the industry is not doing enough to protect whistleblowers. Inspector general recommendations for the Office for Human Research Protections. **Read more** [Special Counsel Lerner leaves office as Trump rejects highly praised whistleblower advocate]

Existing protections might not be enough. [Trump's new VA office to help fire feds faster also could hurt, not protect whistleblowers] about the adequacy of current whistleblower protections ..." the report said. "Elevating this issue would prompt HHS to consider Department of Health and Human Services' protection of whistleblowers. **Read more** [Special Counsel Lerner leaves office as Trump rejects highly praised whistleblower advocate] Therefore, it could help HHS determine whether it should seek a legislative change that enables OHRP and other HHS entities that are not responsible for contract or grant oversight management to receive protected disclosures."

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