

# University was tipped off to possible unauthorized trials of herpes vaccine

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The university that employed a controversial herpes vaccine researcher has told the federal government it learned last summer of the possibility of his illegal experimentation on human subjects. But Southern Illinois University did not publicly disclose the tip or its findings about researcher William Halford's misconduct for months, according to a memo obtained by Kaiser Health News.

Last week, Kaiser Health News reported that Halford conducted an experiment in which he vaccinated patients in U.S. hotel rooms in 2013 without any safety oversight and in violation of U.S. laws, according to patients and emails they provided to KHN to support their allegations.

They told KHN those injections occurred three years before Halford tested a herpes vaccine he created on human subjects in a house in St. Kitts in 2016, again without routine safety oversight. Halford died of cancer at the end of June.

While the university has refused to respond to questions about the 2013 injections, an Oct. 16 memo to the federal government obtained by KHN under open-records law shows that SIU learned of such possible activity at the end of July. According to the memo, Rational Vaccines, the company that Halford co-founded, and another SIU professor disclosed that "human subjects research might have occurred prior to the ... clinical trial in St. Kitts."

SIU reported in the memo to the Department of Health and Human Services and the Food and Drug Administration that its

institutional review board, or IRB, found Halford's activities to be a "serious noncompliance" and said it recommended the university conduct a "confidential" investigation to determine if he committed any other misconduct.

"Dr. Halford willfully and intentionally engaged in human subjects research without the approval and oversight of the IRB, in violation of IRB policies and in violation of applicable law and regulation," SIU wrote in the memo.

Previously, the university had said it was not responsible for Halford's St. Kitts trial because he conducted it independently through Rational Vaccines.

Before releasing the memo to KHN, the university blacked out some of the details. It's unclear whether the "serious noncompliance" involved the 2013 injections or some other unauthorized human subject research.

"This is a very serious matter for the university," said Robert Klitzman, a doctor and director of the master's program in bioethics at Columbia University in New York.

Klitzman said the Office for Human Research Protections (OHRP), the HHS division that oversees compliance with rules on human trials, could halt all of the university's research as a result of the finding. The National Institutes of Health could also freeze its funding to SIU, he added, even though Halford's research was not federally funded.

OHRP and the FDA said they have policies of not discussing potential or ongoing investigations. SIU did not respond to questions.

Several participants from both trials told KHN they have asked SIU for help. They said Tuesday that they felt the university should be informing them of its investigation into unauthorized experiments and its findings.

“Halford tested his vaccine on humans using SIU’s facilities and resources,” said one Colorado woman who has tried to talk to the university about her experience in the St. Kitts trial. “They [SIU] deny knowing anything about it. SIU hasn’t been very forthcoming.”

Klitzman said the university did have a responsibility to the participants who were injected with Halford’s vaccine. Two of them – including the Colorado woman – have filed so-called adverse event complaints with the FDA, saying that Halford’s vaccine may have caused side effects.

“Ethically, the university should contact the participants to let them know that some participants have developed adverse events,” he said.

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