

BACKGROUND

Dr. William Halford was hired by SIU School of Medicine (SOM) in 2007, having been involved in research on the herpes virus since 1992. He performed much of the pre-clinical development of the vaccine in his laboratories at SIU School of Medicine.

In 2012, Dr. Halford formed an independent company called Rational Vaccines (RVX). In May 2015, RVX negotiated a license agreement related to the use of the herpes vaccine developed by Dr. Halford. This license allowed Dr. Halford to use the herpes vaccine for further research as an employee and owner of RVX. SIU's Conflict of Interest Committee reviewed Dr. Halford's conflict of interest disclosure which outlined Dr. Halford working for two separate organizations, SIU and RVX, with two different scopes of work: bench research for SIU and product development for RVX.

While SIU SOM knew that Dr. Halford was employed by Rational Vaccines, SIU did not have knowledge of, input into or oversight of any activities of Rational Vaccines, which operates as an independent company. There was no reason for SIU SOM to weigh in on the clinical trial of the vaccine as the trial was unrelated to SIU SOM and performed independent from the university.

Staff from SIU SOM attended the SIU Technology Expo in October 2016, without knowledge of the details of Dr. Halford's presentation. Upon hearing the presentation, the SIU SOM leadership and faculty in attendance were stunned and amazed by Rational Vaccines' work. Dr. Halford presented that work as the work of RVX, and SIU SOM had no reason to question that representation. Because the work was presented as RVX's work, there was no reason for SIU administrators to question whether RVX had complied with the laws and regulations applicable to that research.

Dr. Halford died in June 2017. Concerns related to Dr. Halford's research protocol were first raised to SIU SOM leadership in July 2017. Once SIU SOM learned of irregularities in Dr. Halford's work with Rational Vaccines, the IRB began investigating Dr. Halford's work in his faculty role at SIU SOM.

The U.S. Department of Health and Human Services (HHS) contacted SIU SOM on September 7, 2017, to request that SIU SOM provide a report of its involvement in the RVX clinical trial. SIU SOM responded to HHS on October 6, 2017. SIU will continue open communication with HHS as our investigation proceeds.

SIU SOM's REVIEW

In August 2017, SIU SOM's Institutional Review Board (IRB) began investigating whether there were any areas of noncompliance with regulatory requirements and institutional policies and procedures with Dr. Halford's work at SIU SOM. SIU is working diligently to conduct this investigation expeditiously as possible. If there are areas of concern, SIU will report those

findings promptly to HHS. We will also communicate our findings with the scientific community and the public.

At the same time, SIU SOM is evaluating all related policies, including conflict of interest policies, and examining the required disclosures and adherence to them. We are also reviewing Dr. Halford's use of SIU resources.

SIU SOM mandates training for our faculty on compliance with federal law and regulations, university policies, codes of ethics and conduct, and research protocols that align with IRB best practices. SIU has technology transfer agreements that lay out expectations for adherence to applicable federal laws and regulations associated with licenses. The university is clear about using university property and facilities only for official university purposes. And we require faculty and researchers to report all conflicts of interest. It is our expectation that these safeguards, guidelines and protocols are adhered to and that faculty reports regarding compliance are timely, accurate and truthful. As part of our review, we will be considering whether changes to reporting are needed, and how well reporting practices align with policy.

In addition, the university has confidential channels for reporting suspected misconduct by faculty and researchers. We are committed to expanding awareness of this policy for SIU SOM faculty, researchers, students, staff and administration, and ensuring that the SIU SOM environment encourages concerned individuals to report any potential violations of ethics, research policies, or legal requirements.