SIU School of Medicine

November 7, 2017

Marisa Taylor
Senior Correspondent
Kaiser Health News
1330 G Street NW
Washington, DC 20005
MarisaT@kff.org

RE: FOIA Dated October 24, 2017 – RESPONSE

Dear Ms. Taylor:

This letter is in response to your request under the Freedom of Information Act (FOIA) (5 ILCS 140/1 *et seq.*) dated October 24, 2017, which was received on the same day. You requested "SIU's Oct. 6th response to HHS" and the "HHS Request to SIU." Your request is granted in part and denied in part.

Enclosed please find a copy of the request from HHS to SIU.

The SIU Response to HHS (hereinafter "Response") is enclosed with redactions because it contains information that is exempt from disclosure pursuant to 5 ILCS 140/7(1)(d)(ii), which exempts disclosure of records which would "interfere with active administrative enforcement proceedings conducted by the public body that is the recipient of the request." Specifically, certain provisions of the Response pertain to an ongoing investigation and pending administrative proceeding and would be detrimental to the process and outcome of the same if released.

The decision that resulted in the redaction of the Response was made by me and my title is Associate General Counsel and FOIA Officer for the School of Medicine.

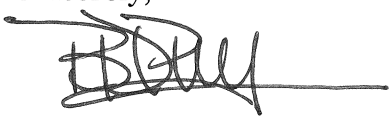
You have the right to have the redacted portions of the Response reviewed by the Public Access Counselor ("PAC") at the Office of the Illinois Attorney General. [See 5 ILCS 140/9.5(a)]. You can file your Request for Review with the PAC by writing to:

Public Access Counselor
Office of the Attorney General
500 South 2nd Street
Springfield, Illinois 62706
Fax: 217-782-1396
E-Mail: publicaccess@atg.state.il.us

If you choose to file a Request for Review with the PAC, you must do so within sixty (60) calendar days from the date of this partial denial letter. [See 5 ILCS 140/9.5(a)]. Please note that you must include a copy of your original FOIA request(s) and this partial denial letter when filing a Request with the PAC.

You also have the right to seek judicial review regarding the redactions of the Response by filing a lawsuit in circuit court of Sangamon County. (See 5 ILCS 140/11).

Sincerely,



BRENDA D. PRYOR
Associate General Counsel/FOIA Officer
SIU School of Medicine
(217) 545-6601, office
bpryor86@siumed.edu

Enclosures

From: Buchanan, Lisa (HHS/OASH) [mailto:Lisa.Buchanan@hhs.gov]
Sent: Thursday, September 07, 2017 11:27 AM
To: Jerry Kruse <jkruse@siumed.edu>
Cc: Alisha Mirabile <amirabile@siumed.edu>
Subject: St. Kitt's Herpes Vaccine Trial

Dr. Kruse,

I am contacting you as the signatory official on the Federal-wide Assurance for Southern Illinois University (SIU) School of Medicine regarding research conducted by a SIU researcher, the late Dr. William Halford. According to a recent press release, Dr. Halford was an SIU researcher as well as the co-founder of the Springfield's Rational Vaccines and is the subject of concerns regarding the conduct of a non-IRB approved clinical trial of a genital herpes vaccine carried out by the company.

As you are probably aware, according to Karen Carlson, SIU spokeswoman, SIU medical school officials were unaware of this trial until it was done and she asserts that the trial was not conducted by Dr. Halford as part of his faculty appointment at SIU. She is quoted as stating "The research in question was run by Dr. Halford in his role as the chief science officer of Rational Vaccines, an independent company, not as a faculty member of SIU School of Medicine."

According to OHRP's records, SIU applies HHS regulations to all of its research, regardless of funding. As such OHRP is requesting a report of SIU's involvement in the trial, if any. Please provide OHRP with the results of SIU's evaluation of its jurisdiction over this research, along with documentation to support your determination no later than***October 6, 2017***.

For guidance on whether your institution would be considered engaged in this research, please refer to OHRP's 2008Engagement of Institution's in Human Subject's Research Guidance Document found at:https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.

Please contact me if you have any questions regarding this request.

Thanks,
Lisa Buchanan

Lisa R. Buchanan, MAOM
Sr. Public Health Analyst
Division of Compliance Oversight
Office for Human Research Protections (OHRP)
1101 Wootton Parkway, Suite 200
The Tower Building
Rockville, MD 20852
240-453-8298 (Office)

SIU School of Medicine

October 6, 2017

VIA E-MAIL:

Ms. Lisa R. Buchanan, MAOM
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Division of Compliance Oversight
Office for Human Research Protections (OHRP)
1101 Wootton Parkway, Suite 200
The Tower Building
Rockville, MD 20852
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Dear Ms. Buchanan:

This letter is in response to your email to me dated September 7, 2017. I respond both as the signatory official on the Federal-wide Assurance of the Southern Illinois University School of Medicine ("SIU") and on behalf of the SIU Institutional Review Board ("IRB") regarding certain research conducted by William Halford, PhD. Dr. Halford was employed by SIU as an Associate Professor of Microbiology and Immunology at the Southern Illinois University School of Medicine until his death on June 22, 2017. You have asked me to report SIU's involvement in the conduct of a non-IRB approved clinical trial of a genital herpes vaccine (the "Trial") carried out by the company Rational Vaccines, Inc. The Trial in question was conducted from March to August 2016 on the island of St. Kitts. In this document, I provide both SIU's evaluation and documentation of its jurisdiction over this research, and other information of interest to OHRP.

On July 31, 2017, Mr. Agustin Fernandez III, Chief Executive Officer of Rational Vaccines, Inc., met with the chair of the SIU IRB regarding the development of the HSV-2 herpes vaccine. Rational Vaccines, Inc. is an independent company created by Dr. Halford and Mr. Fernandez in 2015 to support the development of the HSV-2 herpes vaccine.

SIU first became aware that Rational Vaccines, Inc. had conducted the Trial on October 13, 2016. SIU had not been involved in the development, funding, operation or oversight of the Trial. SIU employees are permitted to, and regularly do, perform work outside of their employment with SIU. Dr. Halford's work with Rational Vaccines, Inc. was performed outside of the scope of his employment. It was SIU's understanding that Rational Vaccines, Inc. had been responsible for the management and oversight of the Trial, including work with a local physician in St. Kitts to monitor participants and obtain the necessary governmental approvals.

Because SIU was not involved in the Trial in any way and viewed it as the business operations of a private company, SIU did not feel that any discussion with Dr. Halford about the Trial was

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warranted. To date, there also has been no indication that Mr. Fernandez or Dr. Halford viewed the activities of Rational Vaccines, Inc. to be the activities of SIU.

[redacted]

During his tenure at SIU, Dr. Halford's HSV-2 herpes vaccine studies were performed on mice and guinea pigs and were overseen by the SIU Institutional Animal Care and Use Committee ("SIU IACUC"). Although Dr. Halford had completed the CITI Human Subjects Protection training in 2014, the IRB determined he did not need to complete the training again in 2016, because he was not conducting any research involving human subjects at SIU. To the best of SIU's knowledge at that time, Dr. Halford's work at SIU on the HSV-2 herpes vaccine was limited to animal research.

[redacted]

Because of Dr. Halford's death and Mr. Fernandez's disclosures, the IRB did feel that an investigation was appropriate to ascertain whether IRB procedures had been followed with respect to Dr. Halford's activities at SIU. To date, SIU has secured and inspected Dr. Halford's office and computers and has arranged for and conducted numerous interviews with SIU researchers and staff to gather as much information as possible about Dr. Halford's research activities. A preliminary review of information has been conducted, and SIU is in the process of evaluating whether a forensic examination of those assets is appropriate to gather additional information.

[redacted]

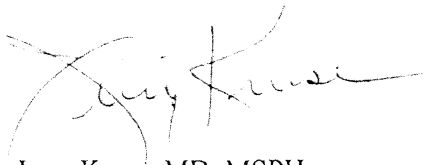
4. Dr. Halford performed a clinical trial in St. Kitts with his company, Rational Vaccines Inc., that was not presented to, overseen or approved by the SIU IRB and the SIU IRB is not the IRB of record for Rational Vaccines, Inc. Based on our investigation, it appears one of the reasons Dr. Halford and Rational Vaccines, Inc. may have chosen a location outside of the United States for the Phase 1 testing of the vaccine was the perception of less vigorous regulatory requirements.

The initial IRB investigation has determined that serious noncompliance with regulatory requirements and institutional policies and procedures occurred. The IRB investigation has closed, and the IRB plans to submit its report to OHRP and the Food and Drug Administration in accordance with the IRB's policies. A further confidential investigation under the Southern Illinois University policy on Research Misconduct, which is based on the Public Health Service (PHS) Policies on Research Misconduct, set forth at 42 CFR 93, is commencing due to additional concerns that have been identified; that investigation is currently ongoing. Our investigation has been somewhat impeded given that Dr. Halford is now deceased, but SIU is working diligently to gather as much information as possible. Should that investigation identify other findings that relate to the areas of concern to OHRP, I will promptly advise you.

I assure you that SIU takes this situation very seriously, and I am committed to identifying any missing controls that facilitated the conduct of a human subject trial without appropriate oversight. If deemed necessary, SIU will develop an effective corrective action plan, and develop, supplement and/or implement additional policies and procedures at both the IRB and departmental level that will further ensure that research at SIU is both safe and in compliance with all regulations.

SIU is committed to compliance with the requirements of conducting safe human subject research and has a history of reporting issues of non-compliance to OHRP. We look forward to continuing working with you and updating you as needed. If you have any questions, please contact me the address, telephone or email listed below or on the first page.

Sincerely yours,



Jerry Kruse, MD, MSPH
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