



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

April 28, 2020

Re: Animal Welfare Assurance
#A3471-01 [OLAW Case 3J]

Dr. Wesley Byerly
Associate Vice President,
Research Integrity and Regulatory Affairs
University of Connecticut Health Center
263 Farmington Ave., ASB
Farmington, CT 06030-1920

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 27, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Connecticut Health Center following up on an initial March 6, 2020 notification by email.

According to the information provided, this Office understands that the University of Connecticut Health Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: a research group conducting animal-related activities without appropriate IACUC review and approval. The final report states on March 5, 2020 a research group was found to be performing sentinel testing without an IACUC protocol. The Attending Veterinarian, IACUC Administrator, and research staff representative met to discuss the incident. It is stated the research staff believed that the sentinel testing was included as part of their quality assurance process to get a gnotobiotic room into use. The research staff was informed the sentinel testing was not part of the quality assurance process and they were not covered under UConn Health Institutional sentinel testing protocol. They were also instructed to cease testing immediately and submit a sentinel testing protocol as soon as possible to be reviewed by the UConn Health IACUC.

The report states the incident was discussed at the March IACUC meeting and the committee determined the research staff did not conduct an intentional act of noncompliance. The research staff submitted a protocol to cover this sentinel testing on March 9th, and it is ready to be approved once an animal biological safety protocol has been submitted and approved.

It is noted that these animal related activities were not supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Connecticut Health Center has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Byerly
April 28, 2020
OLAW Case A3471-3J

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2020.04.28 11:15:26
-04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

UConn HEALTH

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7962
Bethesda, MD 20892-7962

March 27, 2020

Re: PHS Assurance D16-00295 (A3471-01), UConn Health

Dear Dr. Morse-

I am writing to you to provide a final report of an incident of non-compliance at UConn Health. Our IACUC Administrator provided an initial report via email on March 6, 2020.

On March 5, 2020, it was discovered that a research group was performing sentinel testing without an IACUC protocol. The Attending Veterinarian, IACUC Administrator, and research staff representative met to discuss the incident. The research staff informed us that they had believed that the sentinel testing was included as part of their quality assurances processes to get a gnotobiotic room into use. They were told that the sentinel testing was not part of the quality assurance process and they were not covered under the UConn Health institutional sentinel testing protocol because the procedures were different and their staff was not listed on our sentinel protocol. They were informed that they must cease testing immediately and submit a sentinel testing protocol as soon as possible to be reviewed by the UConn Health IACUC.

The IACUC discussed this incident during the March IACUC meeting. It was determined that the research staff did not perform an intentional non-compliance act; they were acting in good faith to do the appropriate testing. They submitted a protocol to cover this sentinel testing on March 9, 2020 which is ready to be approved once an animal biological safety protocol has been submitted and approved.

No federal funds were used in this research.

While all efforts were made to deal with this matter in a timely and meaningful manner, I realize there may be questions that arise following your review of this material. Please feel free to contact me at byerly@uchc.edu or at (b) (6)

Sincerely,

Wesley G Byerly

Digitally signed by Wesley G
Byerly
Date: 2020.04.23 13:17:18 -04'00'

Wesley G. Byerly, Pharm.D.
Associate Vice President, Research Integrity and Regulatory Affairs

cc: (b) (6)
Dr. Kathryn Bayne, AAALAC

Institutional Animal Care and Use Committee
263 FARMINGTON AVENUE, MC 1523
FARMINGTON, CT 06030-1523
PHONE 860.679.3429
FAX 860.679.1005
oaacc@uchc.edu
research.uchc.edu

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Retrieved from Animal Research Laboratory Overview (ARLO)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 24, 2020 8:56 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report of non-compliance, D16-00295/A3741-01

Thanks for this report, (b) (6) We will respond soon.
Axel Wolff

From: (b) (6)
Sent: Friday, April 24, 2020 8:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Final report of non-compliance, D16-00295/A3741-01

Good morning-

Attached please find a final report of non-compliance first reported by email in the beginning of March. My apologies for taking so long into getting this final report to you; as you can imagine, things have been pretty hectic with regard to this pandemic we are experiencing.

If you have any questions, or require any additional information, please do not hesitate in contacting me.

Thank you very much. I hope you are all well and stay safe!

(b) (6)



Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 6, 2020 9:59 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Initial notification of non-compliance A3471-01 / D16-00295

Good morning,

Thank you for the preliminary report. We will open a case file and await the final report.

Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Friday, March 6, 2020 9:14 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Initial notification of non-compliance A3471-01 / D16-00295

Good morning-

Institution: UConn Health
PHS: A3471-01 / D16-00295

I am writing on behalf of my institutional official to inform you of an incidence of non-compliance. Through an email, it was discovered that a PI is performing sentinel testing without a protocol. This sentinel testing is being performed by the research group, not the Institution. The procedures are different from the institutional sentinel protocol and cannot be considered to be part of it.

The researcher, our AV, and I met yesterday approximately 2 hours after this situation was discovered. We informed them that they had to stop all sentinel testing immediately. They were informed that they needed to submit a protocol for this work which needed to be reviewed and approved by the IACUC.

This incident will be discussed by the IACUC during our March IACUC meeting and a final report will be sent after that meeting. There were no federal funds used in this non-compliant event.

If there is any additional information required prior to our submission of a final report, please feel free to contact me.