

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 <u>Home Page</u>: http://grants.nih.gov/grants/olaw/olaw.htm

March 12, 2019

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

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

Dr. Wesley Byerly Associate Vice President for Research Compliance UConn Health 263 Farmington Avenue Farmington, CT 06030

Dear Dr. Byerly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 8, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at UConn Health. According to the information provided, OLAW understands that eight rats failed to receive the post-operative analgesia specified in the protocol because the Principal Investigator (PI) felt the animals were not in pain or distress.

The corrective action consisted of counselling the PI to follow the protocol as written or to submit an amendment to the Institutional Animal Care and Use Committee (IACUC) for review and approval.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair

(b) (6)

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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 20892-7982

March 8, 2019

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

Dear Dr. Morse-

I am writing to you to provide a report of an incident of non-compliance at UConn Health.

On February 14, 2019, while performing post-approval monitoring, it was discovered that a PI was not using analgesia after a non-surgical procedure; the approved protocol stated that Buprenorphine would be given twice per day for two days after a procedure for placement of an orthodontic spring. 8 rats had this procedure performed without the analgesia being provided. When questioned, the PI and research staff indicated that the rats did not appear to be in any pain or distress after the procedure. They stated that this was a "cut-and-paste" error from a protocol in which a surgical procedure was performed which included the use of Buprenorphine. It was the PI's position that this non-surgical procedure did not require the use of analgesics.

The PI was informed that this was a reportable non-compliance to OLAW. The PI was informed that Buprenorphine must be given as described in the approved protocol. It was further discussed that if the PI wanted to discontinue the use of Buprenorphine, the protocol must be modified and the modified protocol must be approved by the IACUC before the use of Buprenorphine could be stopped. This incident was brought to the February IACUC meeting for discussion. There are no federal funds supporting this IACUC protocol.

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 <u>byerly@uchc.edu</u> or at (b) (6)

Sincerely,

(b) (6)

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

(b) (6) cc:

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

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Wolff, Axel (NIH/OD) [E]

From: Sent: To: Cc: Subject:	OLAW Division of Compliance Oversight (NIH/OD) Monday, March 11, 2019 7:01 AM (b) (6) OLAW Division of Compliance Oversight (NIH/OD) RE: Report of non-compliance, PHS A3471-01 (D16-00295)
Thank you for this report, (6) Axel Wolff, M.S., D.V.M.	⁽⁶⁾ We will respond soon.
Deputy Director, OLAW	ъ) (б)

Sent: Friday, March 8, 2019 10:21 AM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: Report of non-compliance, PHS A3471-01 (D16-00295)

Good morning.

I am attaching a report of non-compliance at our institution, UConn Health, PHS A3471-01 (D16-00295) for your review. If you need further information, please feel free to contact me.

Thank you and have a wonderful weekend.

(b) (6)