



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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) 402-7065

December 17, 2019

Re: Animal Welfare Assurance
A3295-01 [OLAW Case 4L]

Dr. Jane E. Strasser
Associate Vice President for Research
University of Cincinnati
P.O. Box 210663
51 Goodman Drive, (b) (4) University Hall
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati. According to the information provided, OLAW understands that following cranial surgery, a rat was given post-operative analgesia at a later time interval than was specified in the protocol. No adverse effects were reported with the animal.

The corrective actions consisted of amending the protocol to include a long acting analgesic, retraining the Principal Investigator (PI) and staff on protocol compliance, and having the Institutional Official send a letter to the PI acknowledging the corrective actions.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution 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



A3295-4L

Jane Strasser, Ph.D.
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Institutional Official
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December 13, 2019

Brent Morse, DVM, DACLAM
Interim Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500 MSC 6910
Bethesda, Maryland 20817

RE: PHS Assurance No. D16-00190 / (A3295-01)

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of an issue of non-compliance discussed at the November 14, 2019 meeting of the University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

Protocol Deficiency – Analgesic Administration - Self-Reported by Responsible Researcher

On October 8, 2019 one rat was anesthetized and administered buprenorphine prior to intracranial surgery. A second dose was given 24 hours later but should have been administered every 8-12 hours. Despite the extended duration between doses, there were no animal welfare concerns reported for this animal post-operatively.

The IACUC considered and discussed the following:

Corrective Actions:

- The PI proposed and submitted a protocol amendment to the IACUC to add a sustained release formulation of the approved analgesic. The amendment was approved on December 9, 2019..
- The IACUC requested that the Principal Investigator (PI) and all lab personnel be retrained by the Attending Veterinarian and IACUC Office to help ensure compliance with the IACUC protocol as it related to surgery and analgesic administration. Retraining occurred on November 26, 2019.
- A letter was sent from the Institutional Official to the PI acknowledging the corrective actions taken to achieve humane treatment and regulatory compliance.

Species: rat
NIH Funding: R01 CA229869
U01 DA039550

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.

cc: George Babcock, Ph.D., Chair, Institutional Animal Care and Use Committee

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 16, 2019 10:06 AM
To: Custer, David (custerda)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Letter of Non-Compliance - UC D16-00190

Thank you for this report, Mr. Custer. We will send a reply soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Custer, David (custerda) <custerda@ucmail.uc.edu>
Sent: Monday, December 16, 2019 9:59 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Babcock, George (babcocgf) <babcocgf@ucmail.uc.edu>; Strasser, Jane (strassje) <strassje@ucmail.uc.edu>
Subject: Letter of Non-Compliance - UC D16-00190

Dear Dr. Morse *et.al.*,

The attached document is a letter from the IO at UC / D16-00190.

David A. Custer
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