



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

November 4, 2019

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

Dr. Jane E. Strasser
Associate Vice President
University of Cincinnati
Office of Research Compliance and
Regulatory Affairs
P.O. Box 210567
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 29, 2019 letter regarding three separate noncompliant incidents with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). Each incident is being handled as its own individual case, and this letter is the response for the first of the three incidents. According to the information supplied, OLAW understands that 18 mice did not receive pain medication after subcutaneous osmotic minipump implantation surgery per protocol. It was reported that the involved animal activity was PHS supported.

Corrective actions included meeting with the principal investigator (PI) who acknowledged that no further surgeries would be performed until a protocol amendment was reviewed and approved. The PI submitted a protocol amendment to include a single pre-emptive dose of analgesics which was reviewed and approved by the IACUC. The PI and laboratory members are to be retrained with review of the protocol and emphasis on the analgesic administration section. Please ensure that this retraining has occurred and contact our office if this was not carried out as described.

Please be advised that OLAW recommends prompt preliminary reporting of noncompliance issues with submission of a final report once corrective action has been taken. Additionally, reports of noncompliance to OLAW should include dates of occurrence when describing each incident. Please include this information in future submissions. Based on the information provided, OLAW concurs with the actions taken by the institution and IACUC to address this incident and adhere to the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact



Jane Strasser, Ph.D.
 Associate Vice President for Research
 University of Cincinnati
 PO Box 210663
 51 Goodman Drive
 540 University Hall
 Cincinnati, OH 45221-0663

Phone: (513) 558-5034
 Fax: (513) 558-0549
 Jane.Strasser@uc.edu

July 29, 2019

Axel Wolff, M.S., D.V.M.
 Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 6700B Rockledge Drive, Suite 2500 MSC 6910
 Bethesda, Maryland 20892

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

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of three issues of non-compliance discussed at the April 11 and May 9, 2019 meetings of the University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

1) Post-surgical analgesics were not administered to mice as described in the approved protocol.

The veterinary staff noted that 18 mice that had undergone a minor surgical procedure (subcutaneous osmotic minipump implantation) did not receive peri-operative analgesics as described in the approved IACUC protocol.

Corrective Actions:

- The IACUC Office staff met with the PI and informed him that analgesic use was required. In addition, the PI was instructed to submit an amendment to his protocol if he needed to withhold analgesics for scientific reasons. The PI confirmed that no further surgeries would be conducted until the protocol amendment was reviewed and approved by the IACUC.
- After consultation with the AV and review of the literature, the PI amended his IACUC protocol to include a single pre-emptive dose of analgesics for the subcutaneous osmotic minipump implantation surgery.
- The IACUC reviewed and approved the amendment.
- The IACUC mandated that the PI and lab be retrained by reviewing the protocol with emphasis on the analgesic administration section.
- A letter was sent from the IO to the PI acknowledging the actions that were taken toward achieving regulatory compliance.

Species: mouse
NIH Funding: R01HL141404-01

2) Post-surgical analgesics not administered to mice as described in the approved protocol.

Upon review of the surgical cage cards, the veterinary staff noted that post-operative analgesics had not been administered to 19 mice.

There were no signs of pain or distress in the mice on evaluation.

Corrective Actions:

- The lab responded that a new lab member inadvertently failed to document the provision of the initial post-operative dose of analgesics. The second dose, per the IACUC protocol, had not been provided.
- The IACUC mandated that the IACUC office staff provide retraining to the PI and lab staff by reviewing the protocol with emphasis on the analgesic section.
- A letter was sent from the IO to the PI acknowledging the actions that were taken toward achieving regulatory compliance.

Species: mouse

NIH Funding: 5 R01 HL132111-01-03

3) Protocol Deficiency – Animal Cage Misidentification

A new post-doctoral fellow inadvertently took one cage containing two rats that belonged to another PI and transported them to an approved satellite procedure location. The animals underwent a non-survival surgical procedure and were subsequently euthanized.

Corrective Actions:

- The IACUC mandated that the PI draft a corrective action plan to prevent a similar incident from recurring in the future.
- The animal charges and protocol database properly debited and credited the each PI's animal use numbers.
- A letter was sent from the IO to the PI acknowledging the actions that were taken toward achieving regulatory compliance.

Species: rat

NIH Funding: 1 R01 HL135122-01A1

1 R01 HL135122-01A1

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.
Institutional Official

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, July 29, 2019 1:09 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Babcock, George (babcocgf); Strasser, Jane (strassje)
Subject: RE: Report of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Thank you for providing this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Monday, July 29, 2019 12:59 PM
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: Report of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Dear Dr. Wolff, *et.al.*,

Please see the attached letter of non-compliance from the Institutional Official of the University of Cincinnati.

(b) (6)

