



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 9, 2019

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

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 an email sent on November 18, 2019 that was provided in response to our November 4, 2019 letter requesting additional information regarding the corrective actions to address the reported incident where a new postdoctoral fellow conducted non-survival surgery on two rats that belonged to a different researcher after inadvertently retrieving the incorrect cage of animals. The email communication included a letter dated August 6, 2019 from the associated principal investigator that described the corrective actions.

The corrective action plan, to be used by any laboratory member needing animals, involved a stepwise procedure that consisted of printing or writing down information for the desired cage of animals, matching the cage information to what was printed or written down, and finally, confirming the principal investigator, sex, and strain on the cage card prior to use or removal from the housing area.

OLAW accepts the actions taken to reduce the likelihood of recurrence of similar incidents and concurs with the submission of this report by the institution to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of these matters and find no cause for further action by this Office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Contact



3295-41

Francis X. McCormack, MD
Director, Pulmonary Division
Department of Internal Medicine
University of Cincinnati
PO Box 670564
Cincinnati, OH 45267-0564

6165 Medical Sciences Bldg.
231 Albert Sabin Way
Phone: (513) 558-4831
Fax: (513) 558-4858
Francis.McCormack.uc.edu

George Babcock
Chair, Institutional Animal Care & Use Committee
Shriners 446 M.L. 0558

August 6, 2019

Dear Dr. Babcock,

In response to the actions that took place in April 2019 the McCormack lab has now instituted the following corrective measures. This protocol will be followed by all McCormack lab personnel that have been approved by LAMS and added to the protocol. Going forward any person in need of animals for their experiment will go through a step-check protocol.

The first step is to write down or print the desired cage of animals.

The second step is to match what was written from step 1 to the cage in animal housing area.

The final step is before the animals are used or removed from the animal housing area the PI, Sex and Strain is confirmed on the pre-printed cage card.

All lab personnel have been updated with the new corrective measures.

Regards,

(b) (6)

Francis McCormack, MD

Na, Jane (NIH/OD) [E]

From: (b) (6)
Sent: Monday, November 18, 2019 9:33 AM
To: Na, Jane (NIH/OD) [E]
Cc: Ward, Joan (NIH/OD) [E]
Subject: UC response to OLAW Case A3295-4I
Attachments: 1233_001.pdf; FXM Response 080619.pdf

Hi Dr. Na,

See the attached letter of response from the PI to the IACUC in regards to the issue of non-compliance related to OLAW Case A3295-4I.

Dave

(b) (6)



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November 4, 2019

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

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. Each incident is being handled as its own individual case, and this letter is the response for the last of the three incidents. According to the information supplied, OLAW understands that a new postdoctoral fellow inadvertently took one cage containing two rats that belonged to a different researcher. Non-survival surgery was performed on both animals who were euthanized at the end of the procedure. It was reported that the involved animal activity was PHS supported.

The IACUC mandated that the principal investigator draft a corrective action plan to prevent a similar incident from recurring in the future. No further information regarding the corrective action plan was provided.

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. Please provide additional information to describe the corrective action plan and date(s) of completion or schedule for correction of all planned actions no later than **December 1, 2019** by submitting a letter via email to jane.na@nih.gov.

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
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PO Box 210663
51 Goodman Drive
540 University Hall
Cincinnati, OH 45221-0663

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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

An affirmative action/equal opportunity institution

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

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: 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.

