



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

October 22, 2018

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

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 October 19, 2018 letter responding to my October 11, 2018 request for additional information about 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 the following:

- 1) The surgery in question, for which post-operatives analgesics were not given, was to induce a myocardial infarction.
- 2) The analgesic regimen approved in the protocol called for a pre-emptive dose followed by four additional doses over two days.
- 3) The actual doses given consisted of one post-surgically followed by another one 14 hours later.
- 4) A total of 20 mice was involved.
- 5) Fifteen mice were identified as being bright and alert while five died. The protocol had been approved for expected mortality.
- 6) Once the surgeries resume, the veterinary staff will be involved prior to and throughout the entire procedure to ensure compliance.

Based on its assessment of these explanations, OLAW has a better understanding of the facts surrounding this case and concurs with the actions taken by the institution to comply with the PHS Policy. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Jane Strasser, Ph.D.
Associate Vice President for Research
Institutional Official
University of Cincinnati
PO Box 210663
Cincinnati, OH 45221-0663

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

October 19, 2018

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Bethesda, Maryland 20892

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

Here is our response to your letter (A3295-4F) dated October 11, 2018 requesting additional information.

1. The surgery performed was a myocardial infarction (MI) model created by ligation of the left anterior descending coronary artery.
2. The approved protocol administered a pre-emptive dose of buprenorphine preceding surgery with subsequent doses every 8-12 hours for 48 hours (5 total doses).
3. The researcher gave one post-surgical dose immediately after surgery followed by a dose 14 hours later (2 total doses).
4. Twenty total mice from several surgical sessions were recovering from MI surgery at the time of the incident.
5. At the time of the incident, 15 animals appeared bright, alert, and responsive, the remaining 5 were found dead. This is within the anticipated mortality rate for the procedure (30-50%) in the approved protocol.
6. The laboratory has not performed procedures in the intervening time. Veterinary staff will be involved in advance of (and throughout) procedures until confident that the researchers understand and are following the guidelines and protocol.

Species: mouse / rat
NIH Funding: 5 R01 HL087861
5 R01 GM112930

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.

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

An affirmative action/equal opportunity institution

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 19, 2018 12:30 PM
To: Custer, David (custerda)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Response to Inquiry from UC A3295-01 - Letter A3295-4F

Thank you for this letter, Mr. Custer. We will respond shortly.
Axel Wolff

From: Custer, David (custerda) [mailto:custerda@ucmail.uc.edu]
Sent: Friday, October 19, 2018 11:38 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: Response to Inquiry from UC A3295-01 - Letter A3295-4F

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

Please see the attached letter representing the response to previous inquiry letter (A3295-4F) from the Institutional Official of the University of Cincinnati.

David A. Custer

Interim-Director, Animal Regulatory Compliance
IACUC Office
Office of Research Integrity
University of Cincinnati
P.O. Box 210572
Cincinnati, OH 45221-0572
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October 11, 2018

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

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 October 2, 2018 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 post-surgical analgesics were not given to mice and rats.

The corrective action consisted of counseling the investigator on the requirement for providing analgesics as stated in the approved protocol. The animal use privileges were permanently revoked for the individual responsible and this person has left the laboratory. The laboratory staff was directed to read the protocol and animal use policies, the laboratory is being actively monitored by the Principal Investigator, the veterinarian is consulted prior to the conduct of surgery, and the laboratory manager will oversee all surgeries. An Institutional Animal Care and Use Committee (IACUC) post-approval monitoring assessment will be conducted and the PI will contact the veterinarians and IACUC office before a laboratory member conducts a new procedure.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. In order for this Office to have a complete understanding of this case, please provide the following additional information:

- 1) What type of surgery was involved?
- 2) What was the post-operative analgesic that was to be given and with what frequency?
- 3) Over what length of time were analgesics not given?
- 4) Approximately how many rats and mice were involved?
- 5) Were the animals subjected to pain/distress due to the lack of analgesics?
- 6) Has subsequent monitoring of the laboratory determined that activities are now conducted in accordance with the protocol?

Please provide the requested information by **November 2, 2018**.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Jane Strasser, Ph.D.
 Associate Vice President for Research
 Institutional Official
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 PO Box 210663
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 Fax: (513) 558-0549
 Jane.Strasser@uc.edu

October 2, 2018

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 formally advising you of a compliance concern that was discussed at both the August 9 and September 13, 2018 Institutional Animal Care and Use Committee (IACUC) meetings. At the August meeting the IACUC requested that the PI attend the September meeting to provide and review a corrective and preventative action plan with the committee. A preliminary oral report was filed with Dr. Wolff on August 10, 2018. The issues and review are summarized, below.

During a July 17, 2018 PAM audit the vet staff discovered that the use of post-surgical analgesics was not in alignment with the approved protocol.

Corrective Actions: Actions reviewed at the August 9, 2018 Meeting

- The vet staff met with the responsible researcher and immediately reviewed the analgesic administration section of the protocol.
- The IACUC permanently revoked all live animal use privileges (vivarium & satellite areas) of the responsible individual.
- The IACUC expressed concern about the ability of the lab manager to ensure compliance and requested that the PI meet with the committee to provide and review corrective and preventative actions.

Corrective Actions: Deliberations from the September 13, 2018 Meeting

The PI presented the following actions that were accepted by the IACUC:

- The person directly responsible for the noncompliance is no longer in the laboratory.
- The PI mandated that everyone in the lab read the approved animal use protocol and the IACUC policies related to animal care and welfare.

- The PI is more actively monitoring the lab including weekly review of any protocol and/or post-surgical care issues that might arise.
- The lab is consulting with vet staff the day before all surgeries to ensure appropriate planning and care.
- The lab manager will be present for, and oversee all, surgeries performed by the lab.

Additionally the IACUC mandated that:

- The IACUC Office audit the lab in December 2018 to assess protocol knowledge and surgical performance.
- The PI contact the veterinarians and IACUC Office whenever anyone will be performing a procedure that they have not previously done on this protocol.

Species: mouse / rat

NIH Funding: 5 R01 HL087861
5 R01 GM112930

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.

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: Tuesday, October 02, 2018 3:00 PM
To: Custer, David (custerda); OLAW Division of Compliance Oversight (NIH/OD)
Cc: Babcock, George (babcocgf); Strasser, Jane (strassje)
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Thank you for providing this final report Mr. Custer. 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: Custer, David (custerda) [mailto:custerda@ucmail.uc.edu]
Sent: Tuesday, October 02, 2018 2:47 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 A3295-01

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

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

David A. Custer
Interim-Director, Animal Regulatory Compliance
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