



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

August 16, 2018

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

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 August 10, 2018 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati, following up on an initial telephone report on the same date. According to the information provided, OLAW understands that in two different studies, post-operative analgesics were not given to mice as had been described in the protocol. In the second situation, there were also no surgical records present on the cages.

In the first case, the corrective actions consisted of amending the protocol to justify withholding of analgesics and having the Institutional Official (IO) sending a letter of counsel to the Principal Investigator (PI) stressing protocol compliance. In the second case, the PI and staff were retrained, and a letter of counsel was sent by the IO to the PI stressing protocol compliance.

Based on its assessment of these explanations, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy and notes that the Institutional Animal Care and Use Committee is to place a high burden of proof on the PI regarding the scientific justification for withholding analgesics and to consider possible palliative measures. Thank you for informing OLAW about these matters.

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

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

10 August 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 advising you of two issues of non-compliance discussed at the July 12, 2018 meeting 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.

Corrective Actions:

- During a PAM audit it was determined that a laboratory had not followed the approved analgesic regimen. Researchers explained that analgesics interfered with the immune response and was therefore being administered on an as-needed basis.
- The PI was advised to amend the protocol to scientifically justify withholding analgesics. The protocol amendment has been submitted and approved by the IACUC.
- A letter was sent from the IO to PI outlining the corrective actions for remediation with a reminder of the importance of observing protocol compliance and maintaining all aspects of animal welfare.

Species: mouse
NIH Funding: 5 R00 ES021737-04

2) Surgical records and post-surgical analgesics were not administered to mice as described in the approved protocol.

Corrective Actions:

- During a PAM audit it was observed that no surgical records were present on two cages of mice that still had sutures in place. The lab indicated that it was an inadvertent oversight. Upon review it was determined that the lab had also not provided analgesics as described in the protocol
- The IACUC mandated that the IACUC Office and veterinary staff provide retraining to review the protocol specifics with the PI and lab research staff.
- A letter was sent from the IO to PI outlining the corrective actions for remediation with a reminder of the importance of observing protocol compliance and maintaining all aspects of animal welfare.

Species: mouse

NIH Funding: 5 R01 CA197865-01-05

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: Friday, August 10, 2018 1:27 PM
To: Custer, David (custerda)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-Compliance from University of Cincinnati A3295-01

Thank you for this report, Mr. Custer. We will send a response soon.
Axel Wolff

From: Custer, David (custerda) [mailto:custerda@ucmail.uc.edu]
Sent: Friday, August 10, 2018 11:14 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
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
IACUC Office
Office of Research Integrity
University of Cincinnati
P.O. Box 210572
Cincinnati, OH 45221-0572
Tel [REDACTED] (b) (6)
Fax [REDACTED]
Email custerda@ucmail.uc.edu



Initial Report of Noncompliance

By: aw

Date: 8/10/18

Time: 10:00

Name of Person reporting: David Cooper
Telephone #: (b) (6)
Fax #: (b) (6)
Email: (b) (6)

Name of Institution: U of Cincinnati
Assurance number: A3295

Did incident involve PHS funded activity? yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
Deaths after surgery, no post op analgesia, report noncompliance

Species involved: Mice
Personnel involved: _____
Dates and times: _____
Animal deaths: 5

Projected plan and schedule for correction/prevention (if known): _____
Have PI come to IACUC meeting, suggest animal use privileges of surgeon

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY
Case # _____