



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 - 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
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April 18, 2018

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

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 April 16, 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 several mice failed to receive post-operative analgesia. The mice had received preemptive analgesics and were monitored following the surgery.

The immediate action taken upon discovery consisted of the veterinary staff giving analgesics to the mice. The laboratory staff was retrained on analgesic use, the protocol was amended to add a long acting analgesic, a list of post-surgical signs of pain was posted in the procedure room, and the Principal Investigator received a letter from the Institutional Official acknowledging the corrective actions and noting that animal welfare must be promoted.

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 on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Research Compliance Specialist



13295-40

Jane Strasser, Ph.D.
Associate Vice President for Research
Institutional Official
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51 Goodman Drive
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Cincinnati, OH 45221-0567

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Jane.Strasser@uc.edu

April 16, 2018

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge 1, Suite 1051
6705 Rockledge Drive, MSC 7982
Bethesda, Maryland 20852

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 a compliance concern discussed at the March 9, 2018 meeting of the University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

On February 14, 2018, the PI reported that post-surgical analgesics had inadvertently not been given to a small group of mice recovering from telemetry probe implant surgery. The surgical records indicated that pre-emptive analgesics were given and post-operative monitoring had occurred.

Corrective Actions:

- Veterinary staff provided analgesics immediately after the incident was reported.
- The PI retrained all personnel on the protocol on analgesic use on March 1, 2018.
- The PI modified the protocol to include a description of the use of SR buprenorphine as recommended by the AV; the modification was approved on March 1, 2018.
- On March 2, 2018 the PI posted a listing of post-surgical clinical signs of pain in the telemetry housing/procedure room.
- The IO sent a letter to the PI emphasizing the need to promote animal welfare and acknowledging the corrective actions.

Species: mouse / rat
NIH Funding: 5R01-HL031028-02
5U2CDK059630-17

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.

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

Gopee, Neera (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, April 17, 2018 10:43 AM
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

Dear David,

Thank you for this final report. We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Custer, David (custerda) [mailto:custerda@ucmail.uc.edu]
Sent: Monday, April 16, 2018 3:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>¹
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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