



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
Facsimile: (301) 402-7065

March 31, 2017

Re: Animal Welfare Assurance
A3292-01 [OLAW Case 1R]

Dr. Mark B. Taubman, M.D.
Dean, School of Medicine
University Vice President for Health Sciences
University of Rochester
601 Elmwood Avenue, Box 706
Rochester, NY 14642

Dear Dr. Taubman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 30, 2017 letter providing additional information in response to my March 29, 2017 request for additional information regarding a reported instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Rochester. According to the information provided, OLAW understands the following:

- 1) The study in question was not PHS-supported.
- 2) The mice were reportedly not exhibiting clinical signs of pain or distress after not receiving the full analgesic regimen.
- 3) A total of 80 mice were involved.
- 4) The investigator was counseled to follow the protocol and will now use long-acting analgesics and will observe the mice daily.
- 5) The institution had been successfully using long acting opioid analgesics for rodent surgery but the drug is no longer available. The Attending Veterinarian will have the veterinary staff provide a different long acting analgesic for mice undergoing major recovery surgery. This should successfully support management of post-operative pain for surgeries conducted throughout the program. Investigators are reminded about the appropriate provision of analgesia and documentation during semi-annual laboratory visits.

Based on its assessment of these explanations, OLAW has a better understanding of the facts involved in the incident and is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Page 2 – Dr. Taubman
March 31, 2017
OLAW Case A3292-1R

Sincerely,

A handwritten signature in black ink, appearing to read "Axel Wolff, M.S., D.V.M.", with a horizontal line extending from the end of the signature.

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

A3292

Mark B. Taubman, MD
CEO, University of Rochester Medical Center and UR Medicine
Dean, School of Medicine and Dentistry
Senior Vice President for Health Sciences



UNIVERSITY of
ROCHESTER
MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

March 30, 2017

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge Once, Suite 360
67005 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892 – 7982

Ref: Animal Welfare Assurance No. D16-00188

Dear Dr. Wolff:

I am attaching a report from the University Committee on Animal Resource regarding your request for more information on a non-compliance issue sent on March 22, 2017.

Please do not hesitate to contact the Chair of the Committee, Dr. Suzanne Stevens, if you wish further information. You can call the UCAR office at Phone Number or her email address is suzanne_stevens@urmc.rochester.edu.

Yours truly

Mark B. Taubman, M.D.
CEO, URM and UR Medicine
Dean, School of Medicine and Dentistry
University Vice President for Health Sciences

Attachment

THE UNIVERSITY COMMITTEE ON ANIMAL RESOURCES

March 30, 2017

Dear Dr. Taubman

In response to the University of Rochester report of non-compliance to OLAW A3292-01 Case 1R, OLAW requested information on 5 points. Our responses are as follows:

- 1) Is the study in question PHS-supported?
The study was not PHS supported.
- 2) Were the mice exhibiting signs of pain or distress due to not receiving the analgesic?
The mice were given buprenorphine daily including immediately post surgery, but not every 6-12 hours as required by our policy and stated in the protocol. The surgeon did not see any pain after day one and reported that the animals were active, nor were the animals reported for pain by the animal care staff. The animals were identified during a random audit of the analgesia records and were not observed to be in pain at that time.
- 3) How many mice were involved?
80 mice
- 4) Provide a summary of the action plan submitted by the investigator.
The surgeon has been counseled about the need to follow analgesia and observation procedures approved in the protocol and has agreed to do so. The lab will also take advantage of newly available program for administration of long acting buprenorphine that requires daily observation and re-dosing at 48-72 hour intervals if necessary, eliminating the need to disturb animals in the middle of the night for observation and dosing.
- 5) Indicate whether any program-wide action was taken to prevent a similar recurrence in another area of the animal care and use program.
The problem of adequate post-surgical analgesia in mice was addressed several years ago when long acting opiate analgesia (Animalgesics) became available for mice. Widespread use of this product for post surgical analgesia following major recovery surgery by mouse users gave us confidence that post-surgical pain was well managed. Unfortunately due to New York State rules about use of long acting opiates, that product is no longer available for our investigators. Our attending veterinarian has been investigating alternatives and has recently made available a veterinary service that allows the veterinary staff to administer long acting buprenorphine preoperatively

to mice undergoing major recovery procedures that call for it, as is done with virtually all our larger animals. A meeting with our Mouse Users Group suggests that most users are very interested in using this approach. As investigators adopt this alternative we expect to see little if any mismanagement of post-operative pain. In addition, during our routine semi-annual laboratory visits, UCAR reviews with the laboratory personnel the importance and need to observe, provide analgesics and documenting these events on all post-operative animals as stated in their approved protocol.



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March 29, 2017

Re: Animal Welfare Assurance
A3292-01 [OLAW Case 1R]

Dr. Mark B. Taubman, M.D.
Dean, School of Medicine
University Vice President for Health Sciences
University of Rochester
601 Elmwood Avenue, Box 706
Rochester, NY 14642

Dear Dr. Taubman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 22, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Rochester. According to the information provided, OLAW understands that post-surgical mice were only given analgesia once daily, which is contrary to what was described in the approved protocol. The cage card records were falsified to indicate that the analgesics had been given appropriately.

The corrective action consisted of the investigator admitting that the analgesic were not given as required and submitting a corrective action plan to the Institutional Animal Care and Use Committee.

In order for OLAW to have a complete understanding of the facts involved in this incident, please provide the following additional information:

- 1) Is the study in question PHS-supported? If so, provide the grant number(s).
- 2) Were the mice exhibiting signs of pain or distress due to not receiving the analgesics?
- 3) How many mice were involved?
- 4) Provide a summary of the action plan submitted by the investigator.
- 5) Indicate whether any program-wide action was taken to prevent a similar recurrence in another area of the animal care and use program.

Please provide the requested information by **April 24, 2017**.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair

A3292-1R

UNIVERSITY OF
ROCHESTER
MEDICAL CENTER

EASTMAN DENTAL CENTER
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING
STRONG MEMORIAL HOSPITAL
UNIVERSITY MEDICAL FACULTY GROUP

THE UNIVERSITY COMMITTEE ON ANIMAL RESOURCES

March 22, 2017

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge Once, Suite 360
67005 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892 – 7982

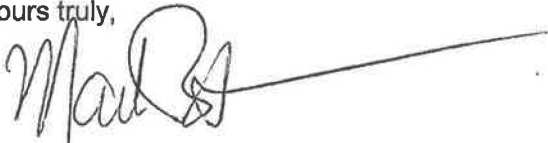
Ref: Animal Welfare Assurance No. D16-00188

Dear Dr. Wolff:

I am attaching a report from the University Committee on Animal Resource regarding a non-compliance issue.

Please do not hesitate to contact the Chair of the Committee, Dr. Suzanne Stevens, if you wish further information. You can call the UCAR office at Phone Number or her email address is suzanne_stevens@urmc.rochester.edu

Yours truly,



Mark B. Taubman, M.D.
CEO, UPMC and UR Medicine
Dean, School of Medicine and Dentistry
University Vice President for Health Sciences

Attachment

THE UNIVERSITY COMMITTEE ON ANIMAL RESOURCES

TO: Mark Taubman, M.D.
CEO, URMC and UR Medicine
Dean, School of Medicine and Dentistry
University Vice President for Health Sciences

FROM: Suzanne Y. Stevens, Ph.D.
Chair, University Committee on Animal Resources

DATE: March 22, 2017

SUBJECT: Report of Noncompliance

During the January 20, 2016 meeting, the University Committee on Animal Resources discussed a serious issue of non-compliance concerning an instance of not following the analgesic therapy in the approved protocol, and the falsification of records regarding the analgesics administered.

The surgeon who performed the surgery on the mice only administered analgesics once per day, which is less than the number of times in the approved protocol. The notes on the animal cage cards indicated more analgesics given, but the access records to the animal room did not match the dates and times. After being questioned, the surgeon admitted the analgesics actually administered were not same as the information on the cage cards.

The investigator apologized for the error and submitted an action plan to avoid these issues in the future. Her response was reviewed and approved at the March 22nd meeting, and the committee voted to report this incident of serious noncompliance to OLAW.

Copy: [redacted] Secondary Individual

SS/jz

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 27, 2017 9:03 AM
To: 'UCAR'
Subject: RE: Noncompliance Report

Thank you for this report, [Secondary Individual]. We will respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: UCAR [mailto:UCAR@URMC.Rochester.edu]
Sent: Friday, March 24, 2017 9:39 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [Secondary Individual] (Counsel) <[Secondary Individual]@admin.rochester.edu>
Subject: Noncompliance Report

To whom it may concern:

Attached you will find a noncompliance report from the University Committee on Animal Resources (UCAR) at the University of Rochester.

Please do not hesitate to contact Dr. Suzanne Stevens (Chair of UCAR) or me if you have any questions. Dr. Stevens contact information is as follows: her direct line is [Phone Number] and her email address is Suzanne_Stevens@urmc.rochester.edu. Emailing Dr. Stevens is the best way to contact her.

Thank you for your attention to this matter.

Sincerely,

[Secondary Individual]
Secretary for University Committee on Animal Resources
University of Rochester, School of Medicine and Dentistry
601 Elmwood Avenue, Box 674
Rochester, New York 14642
Office Phone: [One Number] - Fax Number: [One Number]
[Secondary Individual]@urmc.rochester.edu

UCAR Email: ucar@urmc.rochester.edu