



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 1, 2019

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

Dr. Mark B. Taubman, M.D.
CEO, University of Rochester Medical Center
and UR Medicine
Dean, School of Medicine and Dentistry
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 September 23, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the University of Rochester Medical Center, which had been preceded by a preliminary report to OLAW. According to the information provided, our office understands that on August 14, 2019, a veterinary technician notified the Institutional Animal Care and Use Committee (IACUC) that a laboratory had not administered analgesics to mice prior to a recovery surgery that was part of an NIH funded project.

Immediate corrective actions consisted of administration of analgesics by university veterinarians and monitoring recovery of the mice from surgery. All mice experienced uneventful recoveries. After the incident, the lab associate and Principal Investigator (PI) met with the University Training and Compliance Coordinator to discuss the issues. The associate said they had forgotten to give the medications. Long-term corrective measures proposed by the PI to prevent recurrence consisted of requiring the associate to prepare a presentation on the importance of proper use of pre-surgical analgesics, along with review of institutional policies on surgery and pain management. This lecture was given to all lab members and will be reviewed by the entire lab quarterly. The IACUC reviewed the correction plan and in addition to these measures, required the PI to create a presurgical checklist. The checklist requires that all lab members review the protocol and to document that all necessary preparations are completed in advance of surgeries.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair

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

September 23, 2019

Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear OLAW:

The University of Rochester, in accordance with Assurance **A3292-01** and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident where analgesics was not administered to mice prior to recovery surgery on a protocol entitled: "Role of TNF in osteoclast-mediated bone loss in mice." A NIH funded project. The incident was first reported to OLAW via phone message, on September 23, by Chris Stodgell, PhD, chair of the University Committee on Animal (UCAR).

On 8/14/2019, a veterinarian technician informed UCAR that a lab had not provided the necessary analgesic to mice prior to recovery surgery. The oversight was recognized the following morning by the associate who performed the surgery and immediately contacted our university's veterinarians to request that Buprenorphine-SR be administered to these mice. The mice were then monitored afterwards by the lab as well as the veterinarian technicians. There were no further complications with these mice, and they recovered as expected.

The lab associate and the protocol's PI met with the UCAR Training and Compliance Coordinator to discuss the situation and the reasoning for not providing pre-surgical analgesic. The associate, who had performed this procedure several times, stated that they simply forgot to request to have SR-Buprenorphine administered to the mice.

To address the situation, corrective actions were immediately taken by the PI.

1. The PI and the associate met this the chair of UCAR to discuss the situation and why it happened;
2. The lab associate was instructed by the PI to prepare a presentation for the lab to discuss the proper use of presurgical analgesics, and why it is necessary for the health and well-being of the animals.
3. The presentation would also review applicable UCAR policies pertaining to proper surgical methods and pain management.
4. The presentation was submitted to UCAR's Training and Compliance Coordinator to review for accuracy.
5. The presentation was then made to all lab members at their next lab meeting and will be reviewed by the entire lab quarterly.

The incident was discussed at UCAR's August meeting, and while the committee was impressed by the quick and proactive efforts of the PI and the associate, the committee felt that a more robust action plan was warranted to help ensure such compliance would be sustainable. Thus, the PI created a presurgical checklist that requires all lab members review the protocol and to document that the necessary arrangements and preparations are made prior to the initiation of surgical procedures.

At the UCAR's September meeting, the committee voted to accept the PI's action plan and voted to report the incident to OLAW because of the unrelieved pain that rodents experienced until the following morning.

Thank you for your consideration of this matter.

Sincerely,
(b) (6)

Mark Taubman, MD
Institutional Official
University of Rochester



Initial Report of Noncompliance

By:

Date: 9/24/19

Time:

Name of Person reporting: **Dr. Chris Stodgell (Chair)**

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: **University of Rochester**

Assurance number: **A3292-01**

Did incident involve PHS funded activity?

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

Planning to send final later this week

OFFICE USE ONLY

Case # _____