



DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF

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

March 20, 2019

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 8K]
UMN IACUC #34730A

Dr. Christopher Cramer
Vice President for Research
Institutional Official
University of Minnesota
(b) (4) Johnston Hall - 101 Pleasant St., SE
Minneapolis, MN 55455

Dear Dr. Cramer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your march 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. According to the information provided, OLAW understands that 22 rats failed to receive post-operative analgesia as described in the approved protocol. The animals had received a dose of analgesic immediately following surgery but did not receive the drug at the three day time period.

The corrective action consisted of retraining the laboratory staff and having them ensure that the drugs will be given as stated in the protocol.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3456-8K

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

Mayo Mail Code 79
D-528 Mayo Memorial Building
420 Delaware St. SE
Minneapolis, MN 55455
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March 18, 2019

TO: Axel Wolff, DVM
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: University of Minnesota Animal Care Program D16-00288 (A-3456-01)
NIH Grant Number: R01 NS098781
UMN IACUC #34730A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of non-compliance of an IACUC approved, NIH funded study involving rats. The basis of this report results from a combined semi-annual/surgery inspection. The report outlined that twenty-two rats had not received appropriate analgesic coverage as outlined in the protocol. While an initial injection of pain medication was given after surgery as approved, animals did not receive the 72-hour pain medication regimen as outlined in the protocol. This deviation of protocol occurred between the dates of November 13, 2018 through February 19, 2019.

We want to inform you that we consider this matter closed. A detailed response was received from the laboratory indicating that injectable analgesics will be given on the day of surgery and for 72 hours following the procedure as outlined in the protocol. Further, staff will be retrained on timing of analgesic administration.

Sincerely,

(b) (6)

Christopher J. Cramer, Ph.D.
Vice President for Research
Institutional Official, University of Minnesota
101 Pleasant Street, S.E.
Minneapolis, MN 55455

CC: Brian Crooker, Chair, IACUC
Christine Sivula, Interim Institutional Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 18, 2019 11:47 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-compliance

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Monday, March 18, 2019 10:14 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Chris Cramer <cramer@umn.edu>; Brian Crooker <crook001@umn.edu>; Christine Sivula <sivu0003@umn.edu>
Subject: Report of Non-compliance

Hello Dr. Wolff,
Attached please find a report of non-compliance.
Thank you,

(b) (6)

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(b) (6)