



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

September 11, 2019

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 8Q]
UMN IACUC #36513A

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 September 10, 2019 letter reporting two instances 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 the following about the incidents and the corresponding corrective actions:

- 1) Twelve mice and 28 rats did not receive pre-emptive analgesia two to four hours prior to surgery as required in the protocol but were given the drug immediately before the procedure, which delayed the effect of the analgesic.

Corrective action: The Principal Investigator was contacted and indicated that extended release analgesic will be given as described in the protocol.

- 2) A non-survival surgery to collect tissue was conducted in 39 rats although this procedure was not described in the protocol.

Corrective action: The procedure will not be conducted until the submitted protocol amendment is approved.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A-3456-8Q

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

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420 Delaware St. SE
Minneapolis, MN 55455
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September 10, 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 Numbers:
#36513A—W81XWH-19-1-0075 (BA180023)
#35671A—W81XWH-18-1-0710 (DM170363)
#36812A—W81XWH19C0021 (H2-0402) 18263002
UMN IACUC #36513A, #35671A, #36812A

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/DOD funded study involving mice and rats. The basis of this report results from a post approval monitoring inspection. The report outlined two deviations in protocol. The first was that twelve mice (protocol 35671A) and twenty-eight rats (protocol 36513A) undergoing surgery did not receive the required analgesic two-four hours prior to surgery as described in the protocol but instead were given this analgesic just prior to the procedure which would not have allotted appropriate analgesic coverage. This deviation in protocol occurred in the rats from July 16, 2019 to August 12, 2019 and in the mice from August 6, 2019 to August 16, 2019.

The second deviation in protocol outlined in the report describes a non-survival surgical procedure to remove tissue that was conducted without approval in the protocol. This deviation in protocol occurred in a total of thirty-nine rats (24 under protocol 36513A and 15 on protocol 36812A) from the dates of July 10, 2019 through August 21, 2019.

We want to inform you that we consider this matter closed. A response was received from the PI indicating that the extended release analgesic will be given in the 2-4 hour window as required to ensure analgesic coverage and an amendment has been submitted to the IACUC adding the non-survival surgical procedure for removal of tissue at end of study. Until such time that this amendment is approved, the procedure will not be conducted.

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
Lynn Collura Impelluso, Institutional Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 11, 2019 6:32 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

From: (b) (6)
Sent: Tuesday, September 10, 2019 3:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Lynn Impelluso <impell@umn.edu>; Brian Crooker <crook001@umn.edu>
Subject: Report of non-compliance

Hello Dr. Wolff,

Attached please find a report of non-compliance. Please let me know if you have any questions.
Thank you,

(b) (6)

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(b) (6)