



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) 480-3387

October 24, 2023

Re: Animal Welfare Assurance
A3222-01 [OLAW Case 10]

Aleister Saunders, Ph.D.
Executive Vice Provost for Research and Innovation
Drexel University
3020 Market Street
Philadelphia, PA 19104

Dear Dr. Saunders,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated October 5, 2023, reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University. Your letter supplements the information provided in a preliminary report to this office on August 22, 2023. According to the information provided, OLAW understands that after a review of surgical records, it was confirmed that meloxicam had not been administered after telemeter implantation as indicated in the approved protocol. Upon review of other protocols, the PI self-reported the same non-compliance for a second NIH sponsored approved protocol. This non-compliance impacted a total of 76 rats and 80 mice on the two protocols. There were no signs of any post-operative pain, distress, or adverse events in any of these animals.

Corrective and preventive actions: The PI submitted an amendment for each protocol to forego giving any analgesics for the telemeter implantation procedure. The PI explained the use of analgesics alters the normal immune response and confounds the scientific interpretation of the studies. The PI agreed to use a bupivacaine injection to provide local analgesia before the surgical incision is made. The two protocol amendments to include bupivacaine administration during the telemeter implantations were approved. To prevent this non-compliance from happening in the future, the PI will ensure that any changes to standard, standing procedures made are promptly communicated to all lab members to avoid confusion and minimize the likelihood of non-compliance.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by Drexel University to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2023.10.25 07:19:02 -04'00'

cc: IACUC contact

Ware, Teagan (NIH/OD) [E]

A3222-10

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 20, 2023 10:26 AM
To: lacuc
Cc: OConnor,Michael; Huneke,Richard; Saunders,Aleister; (b) (6)
OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Drexel University (Assurance D16-00138) A3222-1O and A3222-1P Final Reports

Good morning (b) (6)

Thank you for providing these two final reports. We will send official responses soon.

Best,
Teagan

Teagan Ware, MS, PMP
Animal Welfare Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: teagan.ware@nih.gov

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From: lacuc <lacuc@drexel.edu>
Sent: Friday, October 20, 2023 10:18 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: OConnor,Michael <oconnomp@drexel.edu>; Huneke,Richard <rbh25@drexel.edu>; Saunders,Aleister <ajs56@drexel.edu>; (b) (6)
Subject: [EXTERNAL] Drexel University (Assurance D16-00138) A3222-1O and A3222-1P Final Reports

Good Morning,

Drexel University, in accordance with Assurance D16-00138 and PHS Policy IV.F.3., provides the attached final report to OLAW for the following case:

- A3222-1O
- A3222-1P

Please let us know if you require any additional information.

Best,
(b) (6)



DREXEL UNIVERSITY
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10/5/2023

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

Drexel University, in accordance with Assurance D16-00138 and PHS Policy IV.F.3., provides this report of non-compliance regarding a protocol deviation where post-operative analgesics were not provided as indicated in the approved protocol. The species involved include rats (*Rattus rattus*) and mice (*Mus musculus*). This study is sponsored by NIH. The preliminary report was assigned case number **A3222-10**.

After a review of surgical records performed by Drexel's Animal Welfare Education Specialist and discussion with lab personnel, it was confirmed that meloxicam has not been given after telemeter implantation as indicated in the approved protocol. Upon review of other protocols, the PI self-reported the same non-compliance for a second NIH sponsored approved protocol. This non-compliance stems from the oversight by the PI. Previous protocols were approved without the use of meloxicam after the telemeter implantation with the justification that previous studies have demonstrated that the immune system plays an important role in driving sympathetic dysfunction after spinal cord injury, the focus of these protocols. It is known that analgesics affect the immune system. Thus, using analgesics would confound their studies and impair their ability to interpret the data. However, the PI included meloxicam administration after telemeter implantation in the two protocols after addressing IACUC pre-review comments. The PI did not recall adding this since it did not align with previously approved protocols. Overall, this non-compliance impacted a total of 76 rats and 80 mice in the two protocols. There were no signs of any post-operative pain, distress, or adverse events in any of these animals.

No telemeter implantation surgeries were scheduled after the discovery of this non-compliance. The PI submitted a self-report outlining the non-compliance and resolution plan. The PI also submitted an amendment for each protocol to forego giving any analgesics for the telemeter implantation procedure, as they were approved for in previous protocols. The PI explained the use of analgesics alters the normal immune response and confounds the scientific interpretation of the studies. These amendments and the PI's self-report were reviewed by the IACUC at the September 13, 2023 meeting. The IACUC voted to accept the PI's self-report and voted that the amendments required modifications to secure approval. The IACUC wanted either further



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scientific evidence to justify the removal of meloxicam or the addition of another analgesic option.

IACUC Leadership, including the attending veterinarian, met with the PI after the IACUC meeting to discuss other analgesic options for the telemeter implantation. The PI agreed to use a bupivacaine injection to provide local analgesia before the surgical incision is made. The two protocol amendments to include bupivacaine administration during the telemeter implantations were approved on October 2, 2023.

To prevent this non-compliance from happening in the future, the PI will ensure that any changes to standard, standing procedures made are promptly communicated to all lab members to avoid confusion and minimize the likelihood of non-compliance.

Drexel University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Michael O'Connor, MD, PhD, IACUC Chair or Richard Huneke, DVM, attending veterinarian.

Thank you for your consideration of this matter.

Saunders, Aleister

Digitally signed by Saunders,
Aleister
Date: 2023.10.20 09:02:19 -04'00'

Aleister Saunders, Ph.D.
Executive Vice Provost for Research and Innovation
Institutional Official



A3222-10

Initial Report of Noncompliance

By: DCM

Date: 8/22/23

Time: 10am

Name of Person reporting: Mike O'Connor & (b) (6)

Telephone #:

Fax #:

Email:

Name of Institution: Drexel University

Assurance number: A3222-01

Did incident involve PHS funded activity? Yes

Funding component: NIH

Was funding component contacted (if necessary):

What happened:

2 pain study protocols that require meloxicam administration in the protocol, but lab didn't administer it for the implantation; PI self-reported; rats and mice affected; 80 mice and 76 rats; protocol amendment submitted and will be reviewed by IACUC.

Species involved: mice and rats

Personnel involved: lab personnel

Dates and times:

Animal deaths: no

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

Projected submission to OLAW of final report from Institutional Official:

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Case #