



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

August 16, 2023

Re: Animal Welfare Assurance
A3222-01 [OLAW Case 1L]

Aleister Saunders, Ph.D.
Executive Vice Provost for Research and Innovation
Drexel University
3180 Chestnut Street, (b) (4)
Philadelphia, PA 19104

Dear Dr. Saunders,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 17, 2023 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University, following up on an initial telephone report on May 11, 2023. According to the information provided, OLAW understands the following about the incidents and corresponding corrective actions, which all occurred on the same study:

- 1) Sterile gloves were not being used during rodent surgery. Instead, exam gloves were used that were wiped with ethanol. This constitutes a repeat of the same deficiency for this laboratory.
Corrective action: Sterile gloves were obtained.
- 2) Mice were housed in a laboratory, not approved as a satellite facility, for up to three days following surgery.
Corrective action: Mice will no longer be housed in the laboratory for longer than 12 hours.
- 3) Mice were not euthanized at the end of the experiment as stated in the approved protocol.
Corrective action: All mice are now being euthanized at the appropriate timepoint.
- 4) Individuals were conducting animal activities but had not been added to the protocol.
Corrective action: A protocol amendment was approved which added the personnel.

Additional corrective actions: The laboratory was placed under enhanced post-approval monitoring; laboratory staff was provided with a copy of the protocol and amendments, certified understanding of the content, and counseled to adhere to it; a laboratory staffer has been assigned to lead the regulatory procedures within the laboratory and to report any changes during meetings; a binder is now present containing relevant information on protocols, inspection reports, and Institutional Animal Care and Use Committee (IACUC) communications.

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 IACUC to comply with the PHS Policy. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



DREXEL UNIVERSITY
Office of
**Research &
Innovation**

July 17, 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 noncompliance under one study regarding absence of aseptic technique on mice (*Mus musculus*), housing mice (*Mus musculus*) outside of the animal facility for up to three days without IACUC approval, and not sacrificing mice (*Mus musculus*) following the experiments as outlined in the protocol. This study is sponsored by NIH. The preliminary report was assigned case number **A3222-1L**.

During the IACUC Spring Semiannual inspection which took place on April 20, 2023, inspectors noted three issues resulting in serious noncompliance with this study:

1. **Aseptic Technique** - Lab personnel confirmed with the inspectors that they were not using sterile gloves during surgery but instead were using exam gloves that were wiped with ethanol. Sterile surgical gloves were found in the lab at the time of inspection, but they were expired. This lab was cited for using non-sterile gloves in 2018 during the AAALAC site visit and the violation was reported to OLAW (Office of Laboratory Animal Welfare) making this issue a repeat offense. In the Principal Investigator (PI) response to the 2018 citation, the deficiency was acknowledged, and he stated that sterile gloves were purchased for use during surgeries.
2. **Unapproved Satellite Housing** - The lab staff reported that they housed mice (*Mus musculus*) in the lab for up to three days after surgery for monitoring. No records of husbandry or environmental parameters were maintained. The approved protocol indicated that the animals would remain in the lab on a heating pad in a recovery cage until sternal recumbency is achieved. Satellite housing outside of animal facility for longer than 12 hours was not approved by the IACUC.
3. **Experiment Timeline Deviation** - Inspector found a few mice (*Mus musculus*) with a cannula implant in the brain. The surgery date noted on cage ranged from September - December 2022. According to the timeline on the protocol "These experiments will take between 21-60 days " which would be followed by sacrificing the mice. The experiment had ended, but the lab staff had not euthanized the mice.



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A self-report was submitted by the Principal Investigator (PI) on May 21, 2023, outlining his understanding of what happened and a resolution plan. During the investigation of the non-compliance, it was discovered that two lab members mentioned in the self-report were not officially approved to work on the protocol. The amendment to add personnel originally started on September 18, 2022; however, it was not completed or approved. The PI was notified of this non-compliance on May 22, 2023, and was also informed that these lab members could not work on this protocol until the amendment was resubmitted with the required information and approved. The personnel amendment was revised, resubmitted, and approved on May 23, 2023.

The self-report was reviewed by the IACUC at its June 14, 2023 meeting and the committee voted to request additional information about training and oversight from the PI, and to have the Drexel Animal Welfare Education Specialist perform thorough post approval monitoring (PAM) visits every three months, in addition to the semiannual inspections, which will cover all active protocols. PAM visits will continue until the IACUC deems that culture has shifted in the lab to that of compliance.

A letter including the additional information requested by the IACUC was received on June 21, 2023. On July 12, 2023, the IACUC reviewed the updated letter and voted to accept the plan. The accepted plan included the following:

Reason for occurrence

The PI explained that due to the loss of an R01 grant renewal, the lab lost experienced personnel. After obtaining an R21 and R01 grant in 2022, the lab was able to recruit several new laboratory personnel. The new laboratory personnel, despite receiving IACUC required training, did not have a good understanding of the protocols and IACUC policies which resulted in the three noncompliance items noted.

Non-Compliance Resolution

As of May 2, 2023, the PI has spoken to the lab members about the three noted non-compliance items and re-emphasized that these were in violation of the protocol. The PI ordered sterile gloves to be used during surgeries, mice were no longer being held in the laboratory for up to three days after surgery, and mice were sacrificed upon the completion of experimentation timeline, including those identified at the inspection.

Preventative Measures

All laboratory personnel received a printed copy of the protocol and approved amendments and were required to thoroughly review and sign the documents. The PI has updated the regulatory procedures within the laboratory. A graduate student has been assigned to be the lead regulatory contact within the laboratory and will provide regular updates at the weekly lab meetings regarding all approved changes to the protocols or regulatory information. Furthermore, a regulatory binder has been created, which houses the active approved protocol and amendments, as well as all inspection reports, personnel amendments, and other IACUC communications. This



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binder will be updated regularly and will be provided to all new/visiting laboratory personnel that rotate through the laboratory for review.

On July 7, 2023, the Animal Welfare Education Specialist performed an educational PAM visit to review the laboratory surgery SOP and the IACUC Surgery and Post-Care Policy for Rodents with the PI and all laboratory personnel. The Animal Welfare Education Specialist will observe surgeries within the upcoming weeks and will continue to visit the laboratory every three months.

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: 2023.08.03 14:54:57 -04'00'

Aleister Saunders, Ph.D.

Executive Vice Provost for Research and Innovation

Institutional Official

Professor, Department of Biology

<https://drexel.edu/coas/faculty-research/faculty-directory/Saunders/>

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 4, 2023 9:34 AM
To: Iacuc
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Drexel University (Assurance D16-00138) A3222-1L Final Reports

Good morning (b) (6)

Thank you for sending us this final report for case A3222-1L and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: Iacuc <iacuc@drexel.edu>
Sent: Thursday, August 3, 2023 3:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Saunders, Aleister <ajs56@drexel.edu>; (b) (6) Huneke, Richard <rbh25@drexel.edu>; OConnor, Michael <oconnomp@drexel.edu>
Subject: [EXTERNAL] Drexel University (Assurance D16-00138) A3222-1L Final Reports

Good Afternoon,

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:

- A3222-1L

Please let us know if you require any additional information.

Best,
(b) (6)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.



A3222-1L

Initial Report of Noncompliance

By: (b) (6)

Date: 5/11/23

Time: 230

Name of Person reporting: (b) (6)

Telephone #:

Fax #:

Email:

Mike O'connor

Name of Institution:

Drexel U

Assurance number:

A3222

Did incident involve PHS funded activity? yes

Funding component:

Was funding component contacted (if necessary):

What happened?

- 1) Lab personnel not using sp gloves. Repeat
- 2) Mice housed in lab for 3 days, not approved as satellite or as protocol
- 3) Cage cards had wrong information, Problem of exceeding timelines of study.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

IACUC Investigating

Projected submission to OLAW of final report from Institutional Official:

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Case #