



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

July 23, 2019

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

Aleister Saunders, Ph.D.
Senior Vice Provost for Research
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 15, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University. According to the information provided, OLAW understands that a surgical study involving mice and rats used a different anatomical approach than described in the protocol, used a different surgical instrument than described in the protocol, and the monitoring records did not reflect that the animals had been monitored twice daily.

The corrective actions consisted of amending the protocol to accurately reflect the procedures, modifying the post-operative log sheet to include morning and afternoon checks, having the Principal Investigator take direct responsibility for animal care and use, maintaining a document listing the surgical procedures approved on each protocol, and placing the laboratory under enhanced post-approval monitoring.

Based on its assessment of this explanation, 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



A3222-W

July 15th, 2019

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 regarding surgical methods performed on rats and mice which were inconsistent with procedures approved by the IACUC. The Principal Investigator (PI) also failed to maintain records reflecting accurate post-operative monitoring of animals. The work performed on this protocol is supported by NIH grant numbers 2R01NS041596 and F30NS101873.

On 6/28/2019, the PI self-reported the following instances of non-compliance following a routine post approval monitoring meeting with the Animal Welfare Analyst:

- The laboratory performed surgery at an anatomical location inconsistent with what was listed in the approved IACUC protocol. The PI mistakenly wrote the wrong anatomical location into the IACUC approved protocol and did not realize the procedure differed from what they had written. The anatomical location used by the PI in practice was both the standard surgical approach for the laboratory and the most rational approach scientifically. The PI will submit an amendment with the correct anatomical location.
- The PI has IACUC approval to use a specific instrument during surgery. Although the laboratory received training from a collaborator at a different university before beginning the study, they had inconsistent results with the success of the surgery with the use of this instrument. Rather than continue to attempt to perfect the approach as approved, the laboratory decided to use a different, scientifically acceptable method to obtain more reliable results. At the time the PI did not feel that an amendment was necessary as the procedure was consistent with the approved protocol. The PI stated that he realized his mistake and will submit an amendment for this change and consult with the Attending Veterinarian moving forward.

- The approved post-operative care includes monitoring of all animals for symptoms of pain and routine post-operative care twice daily. The laboratory recorded daily observation of the animals, but did not have records set up to accurately reflect that the animals had been monitored more than once per day. The PI noted that they were certain the animals has been checked twice daily, as routine post-operative care required minimum of two daily animal interactions. The post-operative log sheet will be modified to include separate AM and PM checks.

The PI assured the IACUC that issues of non-compliance would not reoccur as the PI would be directly responsible for all aspects of animal care and use covered in their protocol. They also noted they would welcome the Animal Welfare Analyst to review animal care records and monitor surgical compliance on a more frequent basis.

On 7/10/2019, the IACUC discussed the report at a convened meeting. The committee voted unanimously to accept the report and recommend that, in addition to the noted resolution plan, the PI also keep a protocol "cheat sheet" to keep track of which surgical procedures have been approved on each protocol. The IACUC will provide the PI with an example used by other laboratories working on similar projects.

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.

(b) (6)

Aleister Saunders, Ph.D.
Senior Vice Provost for Research
Professor, Department of Biology
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 23, 2019 7:29 AM
To: Iacuc; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Saunders,Aleister; OConnor,Michael; Huneke,Richard; (b) (6)
Subject: RE: Report of Non-Compliance- Drexel University- D16-00138, NIH 2R01NS041596 and F30NS101873

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Iacuc [mailto:iacuc@drexel.edu]
Sent: Monday, July 22, 2019 12:33 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Saunders,Aleister <ajs56@drexel.edu>; OConnor,Michael <oconnomp@drexel.edu>; Huneke,Richard (b) (6)
Subject: Report of Non-Compliance- Drexel University- D16-00138, NIH 2R01NS041596 and F30NS101873

Good Afternoon,

Drexel University (Assurance D16-00138) would like to report a non-compliance for projects sponsored by NIH grant numbers 2R01NS041596 and F30NS101873. Please see the attached letter with a description of the incident and the actions taken in response.

Please let me know if you need any additional information.

Thank you,
(b) (6)

