



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 1P]

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 13, 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 September 18, 2023. According to the information provided, OLAW understands that four cages of rats, which had surgery on August 26, 2022, were discovered on August 15, 2023. The maximum protocol-approved post-surgery survival timepoint was six months. The rats were in good health and did not show any signs of pain or distress. The one-year survival which the lab never intended to exclude and presumed was approved was not included in the current protocol. The activity was PHS funded.

Corrective action: The PI submitted an amendment to add and justify the one-year post surgery time point. The amendment was approved.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by Drexel University to investigate this incident and provide a corrective measure. 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 07:14:32 -04'00'

cc: IACUC contact

A3222-1P

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 20, 2023 10:26 AM
To: iacuc
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: iacuc <iacuc@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
Office of
**Research &
Innovation**

October 13, 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 regarding a protocol deviation involving post-surgery survival timeline. This study is sponsored by NIH. The preliminary report was assigned case number **A3222-1P**.

Four cages of rats, which had surgery on August 26, 2022, were discovered on August 15, 2023. In reviewing the protocol, the longest post-surgery survival timepoint was six months. These rats discovered were nearing a one-year post-surgery recovery. The rats were in good health and did not show any signs of pain or distress.

The PI indicated that a one-year post-surgery survival was a previously approved time point in their ongoing research which was based on guidance and recommendations from clinical consultants. The one-year survival which the lab never intended to exclude and presumed was approved was not included in the current protocol. To rectify, the PI submitted an amendment to add and justify the one-year post surgery time point.

On September 13, 2023, the IACUC reviewed the amendment to add and justify the one-year post-surgery survival to the study timeline. The amendment to the protocol was approved by the IACUC on September 21, 2023.

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.



DREXEL UNIVERSITY
Office of
**Research &
Innovation**

Thank you for your consideration of this matter.

Saunders, Aleister

Digitally signed by Saunders,
Aleister
Date: 2023.10.20 09:02:38 -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/>



A3222-1P

Initial Report of Noncompliance

By: DCM

Date: 09/18/23

Time: 11:00am

Name of Person reporting: (b) (6) and Mike O'Connor
Telephone #:
Fax #:
Email: (b) (6)

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:

Protocol deviation. NIH sponsored; 4 cages of rats discovered on 8/15 with a surgery date of 8/26/22; deviated from protocol timeline of being euthanized 6mos post-surgery; previous protocols had 1yr post-surgery timeline, so lab personnel thought current protocol had same parameters; amendment submitted.

Species involved: Rats
Personnel involved: Lab personnel
Dates and times: Aug. 15, 2023
Animal deaths: No

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

Projected submission to OLAW of final report from Institutional Official:

Final will be submitted within next few days

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Case #