



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

June 21, 2023

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

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 June 16, 2023 letter reporting an instance 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 that animal activities, specifically breeding, continued to be conducted under an expired protocol. The Institutional Animal Care and Use Committee (IACUC) had sent periodic reminders to the Principal Investigator (PI) regarding the impending protocol expiration, but no action had been taken.

The immediate action taken upon discovery consisted of directing the laboratory to separate the mouse breeding pairs and place all the mice on a holding protocol. The protocol was subsequently renewed and the NIH grant was not charged for any unauthorized animal activities. The laboratory manager was counseled to consult with the veterinary staff if the PI is not available should a similar situation occur. The PI has updated the calendar to indicate reminder dates of expiring protocols and the laboratory will regularly review these dates.

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.

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**

A3222-1K

June 16, 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 animal activity after protocol expiration involving mice (*Mus musculus*). This study is sponsored by NIH. The preliminary report was assigned case number **A3222-1K**.

The NIH sponsored protocol expiration on April 21, 2023, with 24 cages remaining on the protocol some of which were breeder cages. When the protocol expired, the Principal Investigator (PI) was not in the lab and not available, and the lab manager did not do anything with the mice until a member of the ULAR staff was spoken to on April 26, 2023, who stated that all breeding must stop. Three breeding pairs that were set up for continuous breeding were separated that day. Litters that were conceived prior to separation, obviously were born, despite the dam being separated from the sire. Based on the fact that pups are born 21 days after conception, one of the dams was likely impregnated the day the pairs were separated. The other two dams were impregnated prior to the protocol's expiration earlier in April. At the time the protocol expired, only continuous breeding occurred. No experimental procedures (surgical or non-surgical) and no handling occurred of any mice after protocol expiration, until notified by ULAR staff to separate breeding pairs. The mice were also transferred to the IACUC/ULAR Orphan Holding Protocol.

In a self-report provided by the PI, the PI received the automated 90 day until expiration notice, the lab manager began to import and draft the renewal protocol on behalf of the PI via proxy access. In an oversight on the part of the PI, the protocol draft was never submitted, and the PI takes responsibility for this oversight. Although the PI could not find the automated 60- or 30-day reminder in their Outlook, there is record of the reminder being sent in the compliance database.

The PI submitted the renewal protocol application to the IACUC to be reviewed at the June 14th meeting. The PI has also rerouted funds from the NIH grant to cover per diem costs after expiration of the protocol.



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Innovation**

The PI and the lab manager have discussed this incident of which PI accepts full responsibility for, have indicated that the lab manager is to go directly to veterinary staff should anything like this occur in the future when the PI is not available.

To prevent this from occurring in the future, the PI has updated their personal calendar and their work calendar to include alerts for the following for all active IACUC protocols under the name: 90 days, 60 days, 30 days prior to expiration, in addition to expiration dates. In addition, the PI will use the IACUC inspections that occur twice per year as a reminder to check in with their active animal use protocols. The PI will review protocol expiration dates with the lab manager at that time and during their regularly scheduled lab administrative 1-on-1 meetings.

On June 14th, 2023, the IACUC reviewed the self-report and the action plan and voted to accept the plan.

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: 2023.06.16
12:51:00 -0400

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: Tuesday, June 20, 2023 7:27 AM
To: iacuc
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Drexel University (Assurance D16-00138) A3222-1K, A3222-1M, A3222-1N Final Reports

Good morning (b) (6)

Thank you for sending us the final reports for cases A3222-1K, A3222-1M, and A3222-1N. Also, thank you for labeling the files with the case numbers, that's greatly appreciated!

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: Friday, June 16, 2023 1:21 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Saunders,Aleister <ajs56@drexel.edu> (b) (6) OConnor,Michael <oconnomp@drexel.edu>; Huneke,Richard <rbh25@drexel.edu>
Subject: [EXTERNAL] Drexel University (Assurance D16-00138) A3222-1K, A3222-1M, A3222-1N 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 cases:

- A3222-1K
- A3222-1M
- A3222-1N

Please let us know if you require any additional information.

Best,
(b) (6)

(b) (6)





A3222-1K

Initial Report of Noncompliance

By: (b) (6)

Date: 5/11/23

Time: 2³⁰

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

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?
Mice brewed on approved protocol, babies born

Species involved: mice
Personnel involved:
Dates and times:
Animal deaths:

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

Transferred to holding protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #