

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 30, 2023

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

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 letter dated June 16, 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 May 31st. According to the information provided, OLAW understands that after a recent protocol expiration on April 25, 2023, a PI transferred 17 cages containing 59 rats to another protocol which is sponsored by NIH. The new protocol did not support breeding and two cages of rats transferred from the expired protocol were breeding cages. The PI was notified on May 18, 2023 and addressed the issue immediately by ceasing all breeding activity. Between these dates two cages of animals were bred (successfully), and weaned, resulting in an additional two cages. NIH funds supported the activity.

Corrective and preventive measures: The PI submitted an amendment to the NIH sponsored protocol to include breeding of the transgenic rats which was approved by the IACUC. To ensure this issue will not arise again, at the completion of the newly modified protocol, if they decide to continue with breeding the transgenic line, they will create a new protocol for breeding purposes only. The PI has also been notified that any NIH funds cannot be used to support unapproved breeding activities.

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 Digitally signed by Brent C. Morse -S Date: 2023,06,30 14:01:50 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact



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 rats (*Rattus rattus*) breeding activity that occurring without IACUC approval. This study is sponsored by NIH. The preliminary report was assigned case number **A3222-1N**.

After a recent protocol expiration on April 25, 2023, a PI transferred 17 cages containing 59 mice to another protocol which is sponsored by NIH. ULAR staff recognized that the new protocol did not support breeding and two cages of mice transferred from the expired protocol were breeding cages. The PI was notified on May 18, 2023 and addressed the issue immediately by ceasing all breeding activity. Between these dates two cages of animals were bred (successfully), and weaned, resulting in an additional 2 cages. The PI submitted an amendment to the NIH sponsored protocol to include breeding of the transgenic rats which was approved by the IACUC on 6/13/2023.

The PI and the lab pride themselves on adhering to animal ethics guidelines and providing high quality animal care. To ensure this issue will not arise again, at the completion of the newly modified protocol, if we decide to continue with breeding the transgenic line, we will create a new protocol for breeding purposes only.

On June 14th, 2023, the IACUC reviewed the self-report and the action plan and voted to/accept the plan. The PI has also notified that any NIH funds cannot be used to support unapproved breeding activities.

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, Ale Digitally signed by Saunders, Aleister Date: 2023.06.16 12:50:17-0400'

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:

lacuc

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 (<u>pronunciation</u>)
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: lacuc <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 < ajs 56@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)



A3222-IN

From:

OLAW Division of Compliance Oversight (NIH/OD)

To:

Iacuc

Cc: Subject: OLAW Division of Compliance Oversight (NIH/OD)
RE: Drexel University D16-00138 - case numbers

Date: Wednesday, May 31, 2023 11:03:37 AM



Since it's a different species and PI, we'll assign this preliminary report to a new case number. This will be OLAW case **A3222-1N**.

Thanks,

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: lacuc <iacuc@drexel.edu>

Sent: Wednesday, May 31, 2023 10:28 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: [EXTERNAL] Re: Drexel University D16-00138 - case numbers

Hi Devora,

Thank you! This is perfect.

We just had a PI submit a self-report explaining that when one of their protocols expired (April 25th), they transferred the rats (*Rattus rattus*) to another one of their active protocols. Due to some miscommunication within the lab, two of the cages transferred were breeding cages and the protocol they were transferred to (NIH funded) does not support breeding. These two cages successfully bred and weaned resulting in two more cages without breeding approved on the new protocol. Once the lab was notified, they ceased breeding and submitted an amendment.

Should I add this to 1K since it is similar in nature or should it get its own case number. This is

a different PI and different species that 1K.

Thank you for your guidance,

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Wednesday, May 31, 2023 10:16 AM

To: lacuc < iacuc@drexel.edu>

Cc: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov>

Subject: RE: Drexel University D16-00138 - case numbers

EXTERNAL.

Good morning (b) (6)

A3222-1K involves baby mice born to parents housed on an expired protocol; mice were transferred to a holding protocol

A3222-1L involves staff not using surgery gloves, mice housed in lab for 3 days which was not approved, cage cards with incorrect information

Hope this helps! 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: lacuc <iacuc@drexel.edu>

Sent: Tuesday, May 30, 2023 10:16 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: [EXTERNAL] Drexel University D16-00138 - case numbers

Good Morning,

We recently submitted two preliminary reports on May 11th that were assigned case numbers A3222-1K and A3222-1L. One listed three non-compliance from one PI and the other was a protocol expiration with the breeding activity. Would you be able to let me know when case number goes with which non-compliance report so I can add these case numbers to the final report?

