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

DATE: July 11, 2022

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Senior Animal Welfare Program Specialist, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (NHLBI #24-22) - Animal Welfare Assurance A4149-01 [Case 16X]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 9, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the NIH Intramural Research Training Program. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the NHLBI Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to use of an expired injectable anesthetic in mice during an ACUC-approved non-survival surgical procedure. The animal incident report states on May 18, 2022, the Animal Program Director (APD) was informed on 10 occasions over the past 6 months mice were administered expired ketamine. The APD investigated the incident, and it was determined no animals experienced any adverse consequences with the use of expired ketamine. In response to the matter, additional training was provided to the laboratory staff regarding the requirement to check the expiration date and an electronic calendar reminder was established to remind the staff of expiration dates. It is understood the ACUC found these corrective actions to be appropriate.

Based on its assessment of this explanation, OLAW understands that the NIH Intramural Research Training Program has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,
Jacquelyn T. Tubbs -S
Digitally signed by Jacquelyn T. Tubbs -S
Date: 2022.07.11 07:16:08 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. James Hawkins

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Monday, July 11, 2022 10:36 AM
To: Gottesman, Michael (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD); Denny, Stephen (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Hawkins, James (NIH/NHLBI) [E]
Subject: OLAW Case A4149-16X
Attachments: OLAW Case A4149-16X.pdf

Good morning Dr. Gottesman,

Attached please find the final response to OLAW Case A4149-16X. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022

A 4149-16X

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

June 9, 2022

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance D16-00602 (NHLBI 24-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Heart, Lung, and Blood Institute (NHLBI) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the use of an expired injectable anesthetic in mice during an ACUC-approved non-survival surgical procedure. The ACUC's Attending Veterinarian concluded no study animals experienced any adverse consequences from the use of the expired anesthetic after reviewing the procedure, examining study records, and interviewing the study researchers and procedure observers.

The event was first reported to the NIH Office of Animal Care and Use by the NHLBI Attending Veterinarian on May 18, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Richard G. Wyatt -S Digitally signed by Richard G. Wyatt -S
Date: 2022.06.13 09:55:33 -04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Hawkins
Dr. Denny

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung & Blood Institute
Bethesda, Maryland 20892

June 9, 2022

TO: Michael M. Gottesman, M.D., Deputy Director for Intramural Research

FROM: Dr. Elizabeth 'Tish' Murphy, Chair, NHLBI ACUC

SUBJECT: Animal Incident Report

In accordance with Assurance D16-00602 and PHS Policy IV.F.3, the NHLBI ACUC provides this report of an incident that occurred involving the care and use of animals in biomedical research

Summary of Incident

On Wednesday May 18, 2022 the Animal Program Director (APD) was notified by the Principal Investigator that on ten occasions over the prior six months mice were given expired ketamine. The NIH Office of Animal Care and Use and the ACUC Chair were notified on the same day. The APD was assigned to investigate the incident. After reviewing the procedures with the lab staff, no animal experienced any adverse consequences to the use of the expired ketamine.

On June 8, 2022 the PI met with the NHLBI ACUC to discuss the issue. The lab staff has been provided additional training regarding the requirement to check the expiration date and an electronic calendar reminder has been established to remind lab staff of the expiration date.

Corrective Action

After ACUC discussion, the proposed resolution was found acceptable. The incident is to be reported to the NIH Office of Animal Care and Use.

Elizabeth Murphy -S Digitally signed by Elizabeth Murphy -S
Date: 2022.06.09 11:16:18 -04'00'

Elizabeth 'Tish' Murphy

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 16, 2022 6:58 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NHLBI 24-22))

Thank you for this report. We will send a response soon.
Axel Wolff

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Wednesday, June 15, 2022 5:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NHLBI 24-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Heart, Lung, and Blood Institute (NHLBI) ACUC address an animal incident involving the use of an expired injectable anesthetic in mice during an ACUC-approved non-survival surgical procedure. The event was first reported to the NIH Office of Animal Care and Use by the NHLBI Attending Veterinarian on May 18, 2022.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 | Phone: (301) 435-2188 | ***NIH . . . Turning Discovery Into Health*** |

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/07/2022