DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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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

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

DATE: March 12, 2019

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

FROM: Deputy Director, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (#01-19) - Animal Welfare Assurance
A4149-01 [Case 12T]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 8, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the National Institute of Neurological Disorders and Stroke, NIH, following up on an initial report on January 17, 2019. According to the information provided, OLAW understands that three mice died and one was moribund due to lack of food in the cage. An investigator had set up the cage and failed to provide food. The problem was not identified by husbandry staff during the daily health checks, which was compounded by the room being on a reverse light cycle which made observations more difficult. Also, some lights were not working at all.

The corrective actions consisted of euthanizing the surviving mouse. Laboratory staff will now use a double check system when setting up cages to ensure that food/water is present. The animal caretaker was issued a disciplinary memo and was counseled on conducting health checks in the low light conditions. The health check schedule was revised so that animals are now sometimes checked under the full light conditions and the lights were repaired.

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 institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

(b) (6)

Axel Wolff, M.S., D.V.M.

cc: Dr. Richard Wyatt
Dr. Stephen Denny
Dr. Marsha Merrill

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

March 8, 2019

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 A4149-01 (NINDS #01-19)

This correspondence conveys the results of an investigation by the National Institute of Neurological Disorders and Stroke (NINDS) ACUC, in accordance with Assurance A4149-01 and PHS Policy IV.F.3. The adverse event involved the failure of staff members to follow IACUC-approved animal husbandry and health monitoring procedures. The incident contributed to the death of four mice.

As noted in the attached NINDS ACUC memorandum, the event was first reported to the NIH Office of Animal Care and Use by the NINDS ACUC Chair on January 15, 2019.

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

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Merrill
Dr. Denny

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Neurological Disorders and Stroke
10 Center Dr. MSC 1414
Bethesda MD 20892-1414

Date: February 28, 2019

From: Acting Chair, NINDS/NIDCD/NCCIH ACUC

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

Subject: Reportable incident involving lapse in animal husbandry

The following is a summary of a reportable incident involving failure to provide food to one cage of mice, the investigative steps taken, and a description of the corrective actions taken.

Summary of the Incident:

On the afternoon of Friday January 11, 2019, during facility supervisor checks, a cage was found in a housing rack containing three dead mice and one moribund mouse. The cage had water but did not have food. The investigators, the facility manager, and the clinical veterinarian who oversees the housing room were immediately contacted. The mouse was euthanized. An investigator had set up this cage late in the day on Tuesday January 8, 2019 and neglected to put food in the cage. This lapse was not detected by the facility staff during routine observations on the 9th, 10th, and 11th.

Summary of the Investigative Steps Taken:

The following business day, the NINDS Animal Program Director, the Acting Chair of the NINDS/NIDCD/NCCIH ACUC, and the NIH Office of Animal Care and Use were notified. The incident occurred in a Shared Animal Facility, for which NINDS takes the lead.

The NINDS Acting Chair also contacted the NIMH ACUC Chair and APD, since the investigator is located in NIMH. All cages in the affected room were changed by facility staff earlier in the day on Tuesday Jan. 8. The investigator set up the new cage late in the day after the caretakers had completed both the cage change and the afternoon health check. The investigators acknowledged their responsibility in failing to provide food when setting up the cage.

The NINDS ACUC Acting Chair also met with the SAF Facility Manager and the Clinical Veterinarian who oversees the housing room in which the incident took place, and also visited the room. The room in which the mice were held is on a reverse light cycle,

meaning the white lights are on from 9:00 p.m. to 9:00 a.m. and automatically turned off from 9:00 a.m. to 9:00 p.m. During this time only red light is available in the room. This is necessary for certain animal behavior studies in species that are nocturnal. This reverse light cycle means that caretakers are not always able to finish their morning routine before the white lights are automatically turned off. Working under only red light is a circumstance that can make observations more challenging. Although familiar with working in this setting, the caretaker failed to detect that the cage did not have food for three days. This failure, rather than the initial lapse by the investigator, appears to be the cause of the mouse deaths. For that reason, the incident is being reported by the NINDS ACUC.

Summary of Corrective Actions Taken:

The NIMH PI of the ASP in question instituted a new policy requiring a double check system so that whenever a lab member is setting up new cages, a second member must be present to make sure food and water are present in the cages.

The SAF caretaker accepted responsibility and expressed remorse. The facility manager said that the employee had no history of problems in the facility. A disciplinary memo detailing the incident was given to the employee and noted in the employee file. A procedural review of the optimal methods for checking cages in the reduced light setting were reviewed with the employee. Going forward, the order in which the caretaker performs morning health checks in the reverse light cycle rooms is now varied. This will prevent any one room from always being checked only in the dark.

It should be noted that some of the lights in the housing area were not working at the time of the incident, and this may have contributed to the difficulty in observing the conditions in the cage. The lighting has been repaired.

Resolution of the Matter:

A report of the incident was presented and discussed by the NIMH ACUC on Feb. 12, and by the NINDS ACUC on February 14, 2019. Neither the NIMH investigator nor the SAF caretaker had a history of noncompliance or poor performance. The investigator's lab has instituted a double-check procedure for setting up new cages, and the SAF caretaker has been retrained and has made modifications to the observation procedures. At this point, both the NINDS and NIMH ACUCs conclude that appropriate actions were taken to help ensure that similar events do not occur in the future, and therefore, this incident can be closed.

(b) (6)

Marsha Merrill, Ph.D.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 11, 2019 12:55 PM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 Reportable Incident - Summary Report: NIH-NINDS (01-19)

Thank you for this report Dr. Denny. 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

From: Denny, Stephen (NIH/OD) [E]
Sent: Monday, March 11, 2019 12:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Reportable Incident - Summary Report: NIH-NINDS (01-19)

Dear OLAW/DCO,

Final reports from the NIH Institutional Official and the NIH National Institute of Neurological Disorders and Stroke ACUC addressing the animal incident referenced below are attached. If you have any questions please contact me via email or the phone number listed below. Thanks, Steve

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Thursday, January 17, 2019 12:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Reportable Incident: NIH-NINDS (01-19)

Dear OLAW/DCO

On January 15th, 2019, the Acting Attending Veterinarian for the National Institute of Neurological Disorders and Stroke informed this office of a reportable animal incident involving the apparent failure of staff members to follow IACUC-approved animal husbandry and health monitoring procedures. The incident contributed to the death of four mice.

The NINDS ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use| Phone: (301) 496-5424

A4149-12T

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 17, 2019 12:56 PM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 Reportable Incident: NIH-NINDS (01-19)

Thanks Steve. We'll open a new case file.
Axel

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Thursday, January 17, 2019 12:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Reportable Incident: NIH-NINDS (01-19)

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On January 15th, 2019, the Acting Attending Veterinarian for the National Institute of Neurological Disorders and Stroke informed this office of a reportable animal incident involving the apparent failure of staff members to follow IACUC-approved animal husbandry and health monitoring procedures. The incident contributed to the death of four mice.

The NINDS ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use | Phone: (301) 496-5424