



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
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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: May 31, 2022

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

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIEHS #15-22) - Animal Welfare Assurance
A4149-01 [Case 16S]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 13, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute of Environmental Health Sciences (NIEHS). According to the information provided, OLAW understands that on April 7, 2022, it was determined that a moribund mouse was improperly euthanized by an animal husbandry technician who did not adequately perform a secondary method of euthanasia following CO2 inhalation and the mouse regained consciousness. It was subsequently euthanized. Skin of the dorsal cervical region was lacerated upon observation.

Corrective and preventive actions included SOP retraining for the individual and husbandry staff performing euthanasia, which has been completed. Hands-on retraining of the individual with periodic proficiency checks has been completed over seven sessions. Additionally, CMB leadership will discuss current euthanasia procedures followed by the husbandry staff to evaluate any potential refinements and the ACUC will send an email to all ASP participants with the CO2 euthanasia SOP highlighting key points including flow rate, duration of CO2 exposure, and secondary methods to ensure death.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse - Digitally signed by Brent C.
Morse -S
Date: 2022.05.31 14:35:55 -04'00'

S
Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Paul Wade, Chair, NIEHS ACUC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

May 13, 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 (NIEHS 15-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Environmental Health Sciences (NIEHS) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure to appropriately conduct a euthanasia procedure on a mouse in accordance with ACUC-approved animal program operating procedures and the ACUC-approved animal study proposal.

The event was first reported to the NIH Office of Animal Care and Use by the NIEHS ACUC Chairman on April 11, 2022.

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

Michael M.
Gottesman -S

Digitally signed by Michael M.
Gottesman -S
date: 20220518 12:44:26 -0400

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Wade
Dr. Denny



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
Website: <http://www.niehs.nih.gov>

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

From: Paul Wade, Ph.D.
NIEHS Animal Care and Use Committee Chair

Date: May 9, 2022

Subject: Reportable Incident of Noncompliance with PHS Policy

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

On April 7, 2022, the Comparative Medicine Branch (CMB), Head, Veterinary Medicine Section (VMS) reported to the Chief, CMB an incident of inappropriate mouse euthanasia by a CMB animal husbandry technician. A moribund mouse was reported to the VMS; the veterinary technician indicated the mouse should be euthanized per the Animal Study Proposal (ASP). The animal husbandry technician performed CO₂ euthanasia in the animal facility procedure room but did not adequately perform a secondary method of euthanasia following CO₂ inhalation and the mouse regained consciousness. The Head, VMS, observed the animal moving when preparing to perform necropsy in the laboratory and euthanized the mouse. Skin of the dorsal cervical region was lacerated upon observation.

The Chief, CMB, reported the incident to the ACUC Program Coordinator. The ACUC Chair was notified and appointed a subcommittee of the ACUC to review the ACUC Program Coordinator's findings. The subcommittee met on April 11, 2022, to review and discuss the incident and the ACUC Chair reported to the NIH Office of Animal Care and Use (OACU).

The subcommittee appointed by the Chair concluded this is a reportable animal welfare concern and recommended SOP retraining for the individual and husbandry staff performing euthanasia, which was completed on April 7, 2022. Further recommendations included hands-on retraining of the individual with periodic proficiency checks. Retraining and evaluations occurred on April 11, 12, 13, 15, 19, 20, and 22, 2022 with the ARS animal husbandry contract trainer, VMS veterinary technician, and module supervisor. Additionally, CMB leadership will discuss current euthanasia procedures followed by the husbandry staff to evaluate any potential refinements and the ACUC will send an email to all ASP Participants with the CO₂ euthanasia SOP highlighting key points including flow rate, duration of CO₂ exposure, and secondary methods to ensure death.

The incident summary, subcommittee findings, and recommendations were presented to the ACUC at the April 28, 2022, ACUC meeting with a quorum of the ACUC present. The committee unanimously agreed that this is a reportable animal welfare incident where conditions that jeopardize the health or well-being of animals resulted in actual harm to an animal. The ACUC further concurred with the proposed recommendations. No minority viewpoints were filed.

The ACUC feels these actions will prevent the occurrence of a similar incident in the future.

(b) (6)

Paul Wade
Chair, ACUC, NIEHS, NIH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 18, 2022 7:07 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIEHS 15-22))

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

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Monday, May 16, 2022 3:07 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIEHS 15-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Environmental Health Sciences (NIEHS) ACUC address an animal incident involving the failure of a research team to appropriately conduct a euthanasia procedure on a mouse in accordance with ACUC-approved animal program operating procedures and the ACUC-approved Animal Study Proposal. The event was first reported to the NIH Office of Animal Care and Use by the NIEHS ACUC Chairman on April 11, 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* |