



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 20892-7982  
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: January 4, 2023

TO: Nina F. Schor, M.D., Ph.D.  
Deputy Director for Intramural Research, NIH

FROM: Deputy Director, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (NIEHS 44-22) - Animal Welfare Assurance  
A4149-01 [Case 17W]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 29, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute of Environmental Health Sciences, NIH. According to the information provided, OLAW understands that three mice died due to lack of water caused by misunderstanding as to which individuals were responsible for providing special water. Different water was being given than what was stated in the approved protocol and the standard operating procedure (SOP), the cage cards did not specify who would provide water, and the special water bottles were not labeled.

The immediate action taken upon discovery consisted of the veterinary staff providing subcutaneous saline injections to the surviving mice and adding water bottles to the cage. These mice recovered uneventfully. The corrective actions consisted of retraining the animal caretaker responsible as well as the rest of the husbandry staff on the SOP and discussing the matter with all key staff in the chain of command. Cage cards will be correctly labeled and all bottles will be identified when containing special water.

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.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: Dr. Richard Wyatt  
Dr. Stephen Denny  
Dr. Paul Wade



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892[www.nih.gov](http://www.nih.gov)

December 29, 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 44-22)

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 a failure to follow the cage labeling and special water bottle re-filling SOPs as referenced in an ACUC-approved study. The SOP noncompliance resulted in the death of three mice.

The event was first reported to the NIH Office of Animal Care and Use by the NIEHS ACUC Chair on September 23, 2022.

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

Nina F. Schor - S	Digitally signed by Nina F. Schor - S Date: 2022.12.29 20:33:25 +05'00'
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Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt  
Dr. Denny  
Dr. Wade



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>

Date: November 30, 2022

To: Nina Schor, M.D.  
Deputy Director for Intramural Research, NIH

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

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.

A group of mice underwent an adrenalectomy surgery on 9/2/2022. One mouse was found dead 9/13/2022 during the daily health check. Three mice were found dead by the veterinary medicine section (VMS) staff on 9/15/22 and it was determined the mice were receiving reverse-osmosis-deionized water instead of saline water per the SOP and Animal Study Proposal (ASP). The remaining animals in the cohort appeared normal and the VMS staff provided SQ saline injections and added saline water bottles to each cage. The VMS rechecked the mice the following morning and all mice were normal.

The facility veterinarian reported the incident to the Animal Program Director the evening of 9/15/2022. The ACUC Program Coordinator and ACUC Chair were both notified 9/16/2022 that the incident was being discussed by the Animal Resources Section (ARS) management, animal husbandry managers and module supervisor. The ARS were unable to identify a miscommunication between the module supervisor and husbandry technician; the technician believed the investigator was responsible for maintaining the special water, as is the case for some treated water or water consumption monitoring, but in those scenarios the cages are marked to indicate the PI responsibilities. The cage cards for the cohort of mice were labeled with a "special water" card but did not indicate the PI would change. Special water bottles are also to be labeled with a sticker and no sticker was present on the bottles, which should have triggered an investigation by the ARS staff to check the water.

The ARS contract management provided an individual training to the animal room technician on Tuesday, 9/20/22 including a review of the SOP for special water. The entire husbandry staff received training on the SOP for special water on 9/29/22. In addition to special cage card labeling indicating "special water", all bottles will be marked or identified with a sticker denoting the special water.

The ACUC members were notified of this incident at the monthly meeting on 9/22/22. The ACUC chair notified the Director of the NIH Office of Animal Care and Use of this incident on Friday, 9/23/22 and the NIEHS Scientific Director on Saturday, 9/24/22. The ACUC discussed the incident and deliberated over whether the incident was a non-compliance and reportable. The ACUC voted unanimously that the incident is reportable to OLAW based upon the OLAW guidance example of reportable situation "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animal by PHS Policy IV.B.7." The ACUC was comfortable with the actions taken by the Comparative Medicine Branch and had no additional recommendations.

(b) (6)

Paul Wade  
Chair, ACUC, NIEHS, NIH

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 30, 2022 11:44 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (NIEHS 44-22)

Good morning Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best,  
Devora

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

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**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Friday, December 30, 2022 11:16 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (NIEHS 44-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute for Environmental Health Sciences (NIEHS) ACUC address a ACUC-approved Animal Study SOP noncompliance which contributed to the death of 3 mice. The incident was reported to OACU on September 23, 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* |