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 (CC #22-22) - Animal Welfare Assurance A4149-01 [Case 17A]

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 CC Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure of husbandry personnel to adequately monitor and report the health status of mice in eleven cages. The animal incident report states on May 12, 2022, a total of 23 mice were found dead and 3 mice were moribund in 11 cages on a mouse rack. There were no reports of animals being ill and the same contract caretaker worked the entire week in the room (May 5-11, 2022). It is stated the caretaker left early on May 11th and did not return on May 12th and a replacement contract caretaken discovered the dead and moribund animals.

The incident was reported and an investigation by a subcommittee of the ACUC commenced. The following corrective actions were implemented in response to the incident:

- The contract animal caretaker was terminated from the contract and will no longer provide support for this facility.
- During the week of May 16, 2022, the caretaker supervisor was counseled on duties and placed on probation.
- The contract program manager was tasked to conduct a time-use analysis of the facility staff and supervisor to assure proper time management and will be providing the needed oversight on this contract task.
- Standard Operating Procedures on husbandry techniques and reporting animal illnesses were reviewed by the contract trainer with the facility staff and supervisor.
- The Institute requested the project manager and the corporate trainer visit the facility to conduct quality assurance/quality control more frequently, and to assess their staff's performance.

It is noted the Clinical Center ACUC endorsed the corrective actions and voted the incident as reportable to this Office. 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 07:21:15 -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. Lisa Portnoy

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

**From:** McCoy, Devora (NIH/OD) [E]
**Sent:** Monday, July 11, 2022 10:39 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]; Portnoy, Lisa (NIH/CC/OD) [E]
**Subject:** OLAW Case A4149-17A
**Attachments:** OLAW Case A4149-17A.pdf

Good morning Dr. Gottesman,

Attached please find the final response to OLAW Case A4149-17A. 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

A 4149-17 A

**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 (CC 22-22)

This correspondence conveys the results of an animal incident investigation by the NIH Clinical Center (CC) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure of husbandry personnel to adequately monitor and report the health status of mice in eleven cages. This lapse in proper health monitoring prevented the implementation of humane endpoints for twenty-three mice.

The event was first reported to the NIH Office of Animal Care and Use by the CC ACUC Coordinator on May 16, 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 09:51:55 -04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Portnoy
Dr. Denny

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov
Clinical Center, AP
Building 10, Room 1-5684
10 Center Drive, MSC 1504
Bethesda, MD 20892-1504
TEL (301) 594-5922
FAX (301) 402-7694

June 1, 2022

To: Michael Gottesman, M.D., Deputy Director for Intramural Research, NIH
From: Peter Herscovitch, M.D., Chair, Clinical Center Animal Care and Use Committee
Subject: Animal Incident Report - Clinical Center 10T10 ACRF facility

Summary of Incident:
On 5/12/2022, in Room 10C127A of the ACRF Facility, 23 dead and 3 moribund mice were found in 11 cages clustered in the same area of a mouse rack. The Room Husbandry Log stated the cages were changed on 5/5/22. The same contract caretaker worked the entire week 5/5/22-5/11/22 with no reports of any animals being sick. On 5/11/22, the caretaker left early due to illness and the contract supervisor signed off for the afternoon checks with no report of issues. On 5/12/22, the caretaker was out sick again, and the contract replacement caretaker found the dead and moribund animals. The dead animals had been cannibalized, leading to the conclusion that they had been dead for several days. This condition was reported the ACUC Coordinator who reported the incident to the Animal Program Director, the ACUC Chair, and the Office of Animal Care and Use on 5/16/22.

Summary of Investigative Steps:
A subcommittee of the ACUC investigated the incident on 5/12/2022. The subcommittee confirmed the facts of the incident as outlined above, following discussions with the contract caretaker, the contractor supervisor, and the contract project officer. Review of the husbandry records also confirmed the stated timeline.

Summary of Corrective Actions:
The following actions were taken on 5/13/22 after an ACUC investigation of the incident:

- The contract animal caretaker was terminated from the contract and will no longer provide support for this facility.
- During the week of 5/16/22, the caretaker supervisor was counseled on duties and placed on probation.
- The contract program manager was tasked to conduct a time-use analysis of the facility staff and supervisor to assure proper time management, and will be providing the needed oversight on this contract task.
- Standard Operating Procedures on husbandry techniques and reporting animal illnesses were reviewed by the contract trainer with the facility staff and supervisor.
- The Institute requested the project manager and the corporate trainer

visit the facility to conduct quality assurance/quality control more frequently, and to assess their staff's performance.

This issue was discussed at the Clinical Center ACUC meeting on 5/18/22; the committee endorsed the corrective measures and voted to report the incident to OLAW. At this point, the CC ACUC has concluded that appropriate actions were taken to ensure that similar events do not occur in the future.

(b) (6)

Peter Herscovitch, M.D.

cc: Dr. Richard Wyatt
Dr. Lisa Portnoy
Dr. Stephen Denny

## Wolff, Axel (NIH/OD) [E]

**From:** OLAW Division of Compliance Oversight (NIH/OD)
**Sent:** Thursday, June 16, 2022 6:47 AM
**To:** Denny, Stephen (NIH/OD) [E]
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)
**Subject:** RE: D16-00602 NIH Animal Incident Report (CC 22-22))

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 5:08 PM
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
**Subject:** D16-00602 NIH Animal Incident Report (CC 22-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH Clinical Center (CC) ACUC address an animal incident involving the failure of husbandry personnel to adequately monitor and report the health status of mice in eleven cages. The event was first reported to the NIH Office of Animal Care and Use by the CC ACUC Coordinator on May 16, 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*** |