



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
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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: September 30, 2022

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

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIA #37-22) - Animal Welfare Assurance
A4149-01 [Case 17N]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 16, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute on Aging. According to the information provided, OLAW understands that on March 11, 2022, four mice were noted by animal care staff as lethargic and were euthanized after consultation with the Co-Investigator. Subsequent discussion revealed that less than four hours earlier the mice were administered an ACUC- approved concentration of a drug designed to cause muscle injury, but at a greater than approved volume. It was subsequently determined that the PI had told the Co-Investigator to administer the higher dose before an amendment was approved.

Corrective and preventive actions:

- Three-week suspension of animal facility access for both the Principal and Co-Investigator.
- All investigators listed on active ASPs from the laboratory must complete the OACU "Using Animals in NIH Intramural Research: REFRESHER" course.
- A NIA veterinarian will speak directly to all lab animal users on the function of ASP's and the importance of conducting only approved procedures.

The conclusions and corrective/preventive actions by the NIA ACUC is reasonable and accepted by OLAW. OLAW agrees that this incident was reportable. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.

Morse -S

Date: 2022.09.30 14:02:21 -04'00'

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Jeffrey Long, Chair, NIA ACUC

A4149-17N



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

September 16, 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 (NIA 37-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute on Aging (NIA) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the administration of a high dose of a test drug to mice which the ACUC had not previously approved. The unapproved dose contributed to the early termination of the study.

The event was first reported to the NIH Office of Animal Care and Use by the NIA Animal Program Director on March 15, 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: 2022.09.16 10:31:57 -04'00'
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Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt
Dr. Denny
Dr. Long



National Institutes of Health
National Institute on Aging
BRC Baltimore, Maryland 21224

April 13, 2022

To: Michael M. Gottesman, M.D., Deputy Director for Intramural Research
From: Jeffrey M. Long, Ph.D., Chair, NIA Animal Care and Use Committee
Subject: Animal Incident Report

In accordance with Assurance D16-00602 and PHS Policy IV.F.3., the National Institute on Aging (NIA) provides this report of an incident that occurred involving the care and use of animals in biomedical research.

SUMMARY OF EVENT:

On March 11th, 2022, four mice were identified by NIA animal care staff as lethargic and were euthanized after consultation with the Co-Investigator. Subsequent discussion revealed that less than 4 hrs. earlier the mice were administered a NIA ACUC approved concentration of a drug designed to cause muscle injury, but at a greater than approved volume. A subcommittee, composed of the APD, NIA veterinarians, and me was formed to investigate.

The investigation revealed that the Principal Investigator of the Animal Study Proposal (ASP) had intentions of submitting an amendment specifying the increased dose. However, they told the co-investigator to administer the higher dose before this was done. During a convened meeting on April 11, 2022, and after consultation with the OACU, the NIA ACUC determined that this represented an OLAW reportable incident.

CORRECTIVE ACTIONS:

To address the situation, the following corrective actions were taken:

- A 3-week suspension of animal facility access for both the Principal and Co-Investigator.
- All investigators listed on active ASPs from the laboratory must complete the OACU "Using Animals in NIH Intramural Research: REFRESHER" course.
- A NIA veterinarian will speak directly to all lab animal users on the function of ASP's and the importance of conducting only approved procedures.

The NIH ACUC feels that these actions will prevent the recurrence of similar events in the future.

Sincerely,

(b) (6)

Jeffrey M. Long, Ph.D.
Chair, NIA Animal Care and Use Committee

McCoy, Devora (NIH/OD) [E]

From: Denny, Stephen (NIH/OD) [E]
Sent: Friday, September 16, 2022 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: D16-00602 NIH Animal Incident Report (NIA 37-22))
Attachments: D16-00602 NIH IO Animal Incident Memo (NIA 37-22).pdf; D16-00602 NIH ACUC Animal Incident Report (NIA 37-22).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute on Aging (NIA) ACUC address an animal incident involving the administration of a non-ACUC approved volume of a drug solution to four mice contributing to the early termination of the study. The incident was first reported to the NIH Office of Animal Care and Use by the NIA Animal Program Director on March 15, 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** |

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 16, 2022 3:44 PM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIA 37-22))

Good afternoon 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

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Friday, September 16, 2022 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIA 37-22))

Dear OLAW/DCO,

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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 |
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