



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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: August 22, 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 #36-22) - Animal Welfare Assurance
A4149-01 [Case 17L]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 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 December 28, 2021, twenty-four mice were discovered which had been administered an unapproved drug, via oral gavage, daily for 13 days. Six of the 24 mice were deemed in poor enough condition that the investigator was instructed to euthanize them by the next day.

Corrective and preventive actions included:

- A 6-week suspension of facility access for the investigator.
- Investigators listed on the involved laboratories' active ASP's must complete the OACU "Using Animals in NIH Intramural Research: REFRESHER" course.
- A time must be scheduled for the NIA Animal Program Director to speak to all animal users in the involved laboratory regarding 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: 2022.08.22 12:17:33 -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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

August 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 36-22)

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 administration of a drug to mice that was not listed on the pertinent ACUC-approved animal study proposal.

The event was first reported to the NIH Office of Animal Care and Use by the NIA Animal Program Director on January 5, 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: 2022.08.16
16:22:30 -04'00'

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

January 12, 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 December 28th, 2021, NIA veterinarians discovered 24 mice were administered, via oral gavage, a drug not listed on the Animal Study Proposal (ASP) daily for 13 days. Six of the 24 mice were deemed in poor enough condition by the NIA clinical veterinarian that the investigator was instructed to euthanize them by the next day. The drug was approved for use in the same strain of mice on a different ASP from the laboratory, but via a different route of administration (i.p.) and frequency (3X, separated by 48 hrs.)

On January 10th, 2022, the convened NIA ACUC thoroughly discussed the incident and concluded these events represent an OLAW-reportable incident of noncompliance.

CORRECTIVE ACTIONS:

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

- A 6-week suspension of facility access for the investigator starting on Jan. 14th, 2022.
- Investigators listed on the involved laboratories' active ASP's must complete the OACU "Using Animals in NIH Intramural Research: REFRESHER" course.
- A time must be scheduled for the NIA APD to speak to all animal users in the involved laboratory regarding the importance of conducting only approved procedures.

The NIH ACUC feels that these actions will help 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: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 17, 2022 7:49 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIA 36-22)

Good morning Dr. Denny,

Thank you for sending us this report and we will send a 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: Tuesday, August 16, 2022 5:38 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIA 36-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH NIA ACUC address an animal incident involving mice. The event was first reported to the NIH Office of Animal Care and Use by NIA Animal Program Director on January 25, 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** |