



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: October 3, 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 (NINDS #41-22) - Animal Welfare Assurance
A4149-01 [Case 17S]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 21, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute of Neurological Disorders and Stroke. According to the information provided, OLAW understands that on May 27, 2022, the institute was notified of an incident in which four mice were observed to be in poor health by the vet staff. Two of the mice improved with supportive care, but two mice died. It was subsequently determined that the mice had been treated with tamoxifen, but the cage was not labeled to indicate this chemical hazard and it was not included in the protocol.

Corrective and preventive actions: The investigators involved were counseled regarding: 1) the requirement to follow the procedures as approved in the protocol, including appropriate safety-related signage and interventions and endpoints for procedures with the potential to cause pain or distress, 2) the seriousness of deviating from the protocol, and 3) the importance of submitting an amendment if changes to the protocol become necessary. The PI submitted an amendment which was reviewed and formally approved.

The conclusions and actions by the NINDS ACUC are reasonable and accepted by OLAW. OLAW agrees that this incident was reportable. It is understood that no additional problems have occurred since the incident. OLAW assumes that the incident was reported to the NIH OMS for proper tracking. We also note that similar incidents with tamoxifen have been reported by the NIH IRP within the past 11 months. This may indicate the need for additional emphasis regarding the safe use of this chemical in animal research. 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: 2022.10.03 16:25:20 -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. Marsha Merrill, Chair, NINDS ACUC

A4149-17S



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

September 21, 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 (NINDS 41-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Neurological Disorders and Stroke (NINDS) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the administration of a non-ACUC approved chemical to four mice.

The event was first reported to the NIH Office of Animal Care and Use by the NIA Animal Program Director on March 27, 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: 2022.09.22 19:36:10 -04'00'
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Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt
Dr. Denny
Dr. Merrill



DEPARTMENT OF HEALTH & HUMAN SERVICES

**National Institutes of Health
National Institute of Neurological
Disorders and Stroke**
Bldg. 35A, Convent Dr.
Bethesda, MD 20892

Date: Sept 19, 2022

To: Nina F. Schor, M.D., Ph.D., Acting Deputy Director for Intramural Research

From: Chair, NINDS/NIDCD/NCCIH ACUC

Subject: Animal Incident Report

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

Summary of the Incident:

On May 27, 2022, the APD notified me and OACU of an incident in which four mice were observed to be in poor health by the vet staff. The investigators were consulted and with supportive care, two mice improved but two mice died. Further investigation by the veterinary staff revealed that the animals had been treated with the chemical hazard tamoxifen, but the cage was not labeled to indicate this. In addition, although a previous version of the ASP included tamoxifen use, the current ASP did not. The Chair and APD discussed the situation with the PI who accepted full responsibility for the violation. The PI was reminded that an ACUC-approved amendment would be required if the lab wished to use the drug.

The incident was discussed at a convened ACUC meeting on June 9, 2022. The Committee concluded this was a reportable incident involving failure to adhere to an ACUC-approved protocol.

Corrective Actions:

The investigators involved were counseled regarding: 1) the requirement to follow the procedures as approved in the ASP, including appropriate safety-related signage and interventions and endpoints for procedures with the potential to cause pain or distress, 2) the seriousness of deviating from the ASP, and 3) the importance of submitting an amendment if changes to the ASP become necessary. The PI submitted an amendment which was reviewed at the June 9, 2022 ACUC meeting, and formally approved on June 29, 2022. No additional noncompliance has occurred. The ACUC believes these corrective actions will prevent such incidents in the future.

(b) (6)

Marsha Merrill, Ph.D.

McCoy, Devora (NIH/OD) [E]

From: Denny, Stephen (NIH/OD) [E]
Sent: Monday, September 26, 2022 8:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: D16-00602 NIH Animal Incident Report (NINDS 41-22)
Attachments: D16-00602 NIH IO Animal Incident Memo (NINDS 41-22).pdf; D16-00602 NIH ACUC Animal Incident Report (NINDS 41-22).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 of Neurological Disorders and Stroke (NINDS) ACUC address an animal incident involving the administration of a non-ACUC approved chemical to four mice.

The incident was first reported to the NIH Office of Animal Care and Use by the NICHD ACUC Chairman and the NINDS Animal Program Director on March 27, 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: Wednesday, September 28, 2022 7:05 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NINDS 41-22)

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

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Monday, September 26, 2022 8:28 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NINDS 41-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Neurological Disorders and Stroke (NINDS) ACUC address an animal incident involving the administration of a non-ACUC approved chemical to four mice.

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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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