



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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 (NCI #33-22) - Animal Welfare Assurance
A4149-01 [Case 17R]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 27, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Cancer Institute. According to the information provided, OLAW understands that on April 7, 2022, multiple cages of mice maintained under an approved protocol were noted as having received tamoxifen treatment. The protocol did not contain tamoxifen as a chemical hazard. The facility practice is for the investigator to place a standard hazardous chemical sticker on the cage card. It was subsequently determined that the wrong protocol number was placed on the cage card, thus the facility staff were not aware of the hazardous chemical present in the cages.

The Principal Investigator agreed that a mistake was made and reiterated to their staff to: (i) strictly follow the safety language within the ACUC protocols, and ;(ii) to ensure the appropriate information is displayed on the cage cards, based on a discussion with the NCI DOHS safety representative.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW. OLAW assumes that the incident was reported to the NIH OMS for proper tracking. 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 16:26:58 -04'00'

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Remy Bosselut, M.D., Ph.D., Chair, NCI ACUC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892www.nih.gov

September 27, 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 (NCI 33-22)

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 labeling of multiple cages of mice with an incorrect animal study number. This cage labeling error contributed to the exposure of animal care workers to an ACUC-approved hazardous chemical from mouse cages which were not marked with chemical hazard warnings.

The event was first reported to the NIH Office of Animal Care and Use by the NCI Attending Veterinarian on April 7, 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: 2022.09.28 14:34:26 -04'00'
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Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt
Dr. Denny
Dr. Bosselut



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: 8/10/2022

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

From: Rémy Bosselut, M.D., Ph.D.
ACUC Chair, NCI

Subject: Reportable Animal Incident: Off-protocol animal activity

On April 7th, 2022, multiple cages of mice maintained under an NCI Animal Care and Use Committee- (ACUC) approved animal study protocol were noted with a handwritten note stating "special treatment" describing tamoxifen treatment. The animal study protocol listed on the cage card did not contain tamoxifen nor the facility practice for identifying potentially hazardous chemicals present in the cages. Tamoxifen is usually classified as a chemical hazard on animal protocols and the facility practice is for the investigator to place a standard hazardous chemical sticker on the cage card to alert the caretaker staff of a potentially hazardous chemical.

During the investigation, it was determined that another approved ACUC protocol from the same investigator did contain tamoxifen and appropriate safety language, however, the wrong protocol number was placed on the cage card and that the appropriate labelling procedure of hazardous chemicals did not occur; thus the facility staff were not aware of the hazardous chemical present in the cages.

Despite there being no animal welfare concern associated with this finding, the NCI ACUC determined that the incident should be reported to OLAW as there was a safety risk to the facility staff.

The Principal Investigator agreed that a mistake was made and reiterated to their staff (i) to strictly follow the safety language within the ACUC protocols, and (ii) to ensure the appropriate information is displayed on the cage cards, based on a discussion with the NCI DOHS safety representative.

These safety concerns occurred as the investigator failed to follow language approved by the ACUC and resulted in a potential unsafe working environment in the animal facility. The concerns necessitated the Attending Veterinarian to report this incident to the ACUC Chair and the Office of Animal Care and Use on April 7, 2022. This issue was discussed at the NCI ACUC May 2022 meeting; the committee approved the corrective measures and report of the incident to OLAW.

Please feel free to contact me if you have any questions.

Sincerely,

(b) (6)

Rémy Bosselut, M.D., Ph.D.
Chair, NCI ACUC

Cc: David Bodine, M.D.
Stephen Denny, D.V.M.
Tom Misteli, Ph.D.
Glenn Merlino, Ph.D.
Joshua Kramer, D.V.M., M.S.

McCoy, Devora (NIH/OD) [E]

From: Denny, Stephen (NIH/OD) [E]
Sent: Thursday, September 29, 2022 9:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: D16-00602 NIH Animal Incident Report (NCI 33-22)
Attachments: D16-00602 NIH IO Animal Incident Memo (NCI 33-22).pdf; D16-00602 NIH ACUC Animal Incident Report (NCI 33-23).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH Office of Research Services-Division of Veterinary Medicine ACUC address an animal incident involving the labeling of multiple cages of mice with an incorrect animal study number. This cage labeling error contributed to the exposure of animal care workers to an ACUC-approved hazardous chemical from mouse cages which were not marked with chemical hazard warnings.

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: Thursday, September 29, 2022 11:13 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NCI 33-22)

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: Thursday, September 29, 2022 9:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NCI 33-22)

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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 |
Phone: (301) 435-2188 | *NIH . . . Turning Discovery Into Health* |