



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 20892-7982
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 (NCCIH # 28-22) - Animal Welfare Assurance
A4149-01 [Case 17E]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 10, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Center for Complementary and Integrative Health (NCCIH). According to the information provided, OLAW understands that on April 7, 2022, the ACUC was notified of an incident that occurred the week before which resulted in the deaths of three adult mice. The animals had received an injection of an experimental compound at a higher dose than that listed in the approved ASP. The investigator accepted full responsibility for the violation and gave assurance that higher doses were no longer under consideration by the laboratory.

Corrective and preventive measures: The ACUC Chair met with the investigator to emphasize: 1) the requirement to follow the procedures as approved in the ASP, 2) the seriousness of deviating from the ASP, and 3) the importance of submitting an amendment if changes to the ASP become necessary.

The actions taken to resolve the issues and prevent recurrence were appropriate and accepted by OLAW. 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 12:15:35 -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, NINDS/NIDCD/NCCIH ACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

August 10, 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 (NCCIH 28-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Center for Complementary and Integrative Health (NCCIH) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the administration of a test article at a non-ACUC approved dosage level contributing to the death of three mice.

The event was first reported to the NIH Office of Animal Care and Use by the DVR ACUC Chairman on May 6, 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: 2022.08.10
12:34:16 -0400

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: July 1, 2022
To: Michael M. Gottesman, M.D., 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 April 7, 2022, the APD notified me of an incident that occurred the week before in which three adult mice belonging to NCCIH were found dead by the vet staff. The responsible associate investigator and the PI were notified. Further investigation by the veterinary staff revealed that the animals had received an injection of an experimental compound that was listed in the approved ASP. However, the investigator had used a dose of the compound that was outside of the approved range. The investigator explained that others in the scientific literature had reported using higher doses and therefore did not anticipate any problems. The investigator accepted full responsibility for the violation and gave assurance that higher doses were no longer under consideration by the laboratory.

The incident was discussed at convened ACUC meetings on April 14 and May 12 and with OACU on May 6, 2022. The Committee concluded this was a reportable incident involving failure to adhere to an ACUC-approved protocol.

Corrective Actions:

The Chair met with the investigator to emphasize: 1) the requirement to follow the procedures as approved in the ASP, 2) the seriousness of deviating from the ASP, and 3) the importance of submitting an amendment if changes to the ASP become necessary. The ACUC believes these corrective actions will prevent the occurrence of similar incidents in the future.

(b) (6)

Marsha Merrill, Ph.D.

McCoy, Devora (NIH/OD) [E]

From: Denny, Stephen (NIH/OD) [E]
Sent: Wednesday, August 10, 2022 1:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: D16-00602 NIH Animal Incident Report (NCCIH 28-22))
Attachments: D16-00602 IO Animal Incident Memo (NCCIH 28-22).pdf; D16-00602 ACUC Animal Incident Report (NCCIH 28-22).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Center for Complementary and Integrative Health (NCCIH) ACUC address an animal incident involving mice. The event was first reported to the NIH Office of Animal Care and Use by NCCIH/NINDS/NIDCD ACUC Chairman on May 6, 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, August 10, 2022 3:51 PM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NCCIH 28-22))

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: Wednesday, August 10, 2022 1:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NCCIH 28-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Center for Complementary and Integrative Health (NCCIH) ACUC address an animal incident involving mice. The event was first reported to the NIH Office of Animal Care and Use by NCCIH/NINDS/NIDCD ACUC Chairman on May 6, 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** |