



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: May 16, 2022

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NCCIH #12-22) - Animal Welfare Assurance
A4149-01 [Case 16O]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 29, 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 January 21, 2022, the program was notified of an incident that occurred the day before in which an NCCIH investigator had performed abdominal surgery on two adult mice. Although other surgical sites were described in the approved ASP, the abdominal site was not. The investigator was trained in surgical technique.

Corrective and preventive actions: the Principal and Associate Investigators were notified of the error and that an amendment would need to be approved by the ACUC if they wished to perform this type of surgery. The investigators accepted full responsibility for the violation. The veterinarian reviewed surgical technique with the investigator. The investigators submitted an amendment to include the surgical procedure in their already approved ASP. The amendment was reviewed and approved by the ACUC.

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: 2022.05.16 15:35:24 -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

April 29, 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 Incident - Assurance D16-00602 (NCCIH 12-22)

This correspondence conveys the results of an animal incident investigation by the NIH NINDS-NIDCD-NCCIH ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved a National Center for Complementary and Integrative Health (NCCIH) investigator failing to follow the surgical plan described in the ACUC-approved animal study proposal on two mice.

The event was first reported to the NIH Office of Animal Care and Use by the NIAID-DIR ACUC Chairman on February 2, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Michael M.
Gottesman -S

Digitally signed by Michael M.
Gottesman -S
Date: 2022.05.03 10:23:35 -04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Merrill
Dr. Denny



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Date: April 29, 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 Jan. 21, 2022, a clinical veterinarian notified me of an incident that occurred the day before in which an NCCIH investigator had performed abdominal surgery on two adult mice. Although other surgical sites were described in the approved ASP, the abdominal site was not. The investigator was trained in surgical technique.

The veterinarian notified the Principal and Associate Investigators of the error and informed them that an amendment would need to be approved by the ACUC if they wished to perform this type of surgery. The investigators accepted full responsibility for the violation. OACU was notified of the incident on Feb. 2, 2022.

The situation was discussed at a convened ACUC meeting on Feb. 10, 2022. The Committee concluded this was a reportable incident involving conduct of animal-related activities without appropriate ACUC review and approval.

Corrective Actions:

The veterinarian reviewed surgical technique with the investigator. The investigators submitted an amendment to include the surgical procedure in their already approved ASP. The amendment was reviewed at a convened ACUC meeting on March 10, 2022 and approved on April 29, 2022. The ACUC believes that these corrective actions will prevent the occurrence of similar incidents in the future.

(b) (6)

Marsha Merrill, Ph.D.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 4, 2022 7:26 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NCCIH 12-22))

Thank you for this report, Dr. Denny. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Tuesday, May 3, 2022 1:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Smith, Heather (NIH/OD) [E] <heather.smith@nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NCCIH 12-22))

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 the failure of an investigator to perform surgery on two mice as outlined in the ACUC-approved animal study proposal. The event was first reported to the NIH Office of Animal Care and Use by the NINDS/NIDCD/NCCIH ACUC Chairman on February 2, 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** |