



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
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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 31, 2022

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

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIEHS #16-22) - Animal Welfare Assurance
A4149-01 [Case 16T]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 13, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute of Environmental Health Sciences (NIEHS). According to the information provided, OLAW understands that a surgical pilot study was performed on six mice without ASP approval or transfer of mice to an approved ASP. On April 18, 2022, surgical a surgical procedure was performed on six mice under an approved ASP, but the procedures performed in the pilot study were not approved in an SOP to be included in the ASP and the mice were not transferred to the training protocol prior to the procedure. There were no animal welfare concerns.

Corrective and preventive actions included the ACUC approving an amendment which was submitted to add the surgical SOP to the approved ASP. The ACUC also recommended re-training of the transfer and ACUC approval requirements for the involved personnel and evaluation of the transfer policy regarding collaborations with VMS to simplify and better document the process.

The actions taken to resolve the issue 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

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Brent C.
Morse -S
Date: 2022.05.31 14:44:27
-04'00'

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Paul Wade, Chair, NIEHS ACUC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 13, 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 (NIEHS 16-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute of Environmental Health Sciences (NIEHS) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the conduct of a surgical procedure on six mice which had not been appropriately transferred to a training protocol. Also, the surgical procedure was not described or listed in an ACUC approved animal study proposal.

The event was first reported to the NIH Office of Animal Care and Use by the NIEHS ACUC Chairman on April 18, 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: 2022.05.16 10:42:56 -0400

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Wade
Dr. Denny



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
Website: <http://www.niehs.nih.gov>

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

From: Paul Wade, Ph.D.
NIEHS Animal Care and Use Committee Chair

Date: May 9, 2022

Subject: Reportable Incident of Noncompliance with PHS Policy

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

A surgical pilot study was performed by Comparative Medicine Branch (CMB) Veterinary Medicine Section (VMS) personnel April 18, 2022, on six mice under Animal Study Proposal (ASP) 2015-0023 without ASP approval or transfer of mice to an approved ASP. A trainee in the Reproductive & Developmental Biology Laboratory (RDBL) Pregnancy and Female Reproduction group met with VMS staff to discuss alternative surgical decidualization methods. VMS developed the surgical technique and SOP under 85-06, per the approved ASP and a surgical SOP was submitted to the ACUC for review at the April 28, 2022, ACUC meeting. On April 18, 2022, surgical decidualization was performed on six mice under ASP 2015-0023. The procedures performed in the pilot study were not approved in the approved ASP and the mice were not transferred to the training protocol prior to assisting the PI. An Animal Resources Section (ARS) staff member reported the incident to the ACUC office on April 21, 2022.

The ACUC Program Coordinator reported the incident to the NIEHS Animal Program Director (APD) and the ACUC Chair. A meeting was held with the VMS, APD, and ACUC Program Coordinator. All participants agreed that this incident was a failure to transfer the mice to 85-06 or to amend 2015-0023 prior to conducting the surgical pilot. Following clarifications on the ACUC requirements, an amendment was submitted to add the surgical SOP to 2015-0023 along with an animal transfer request for the six mice. There were no animal welfare concerns and the mice were euthanized per the pilot study endpoint. The surgical SOP for decidualization and the amendment to 2015-0023 were reviewed and approved by the ACUC April 28, 2022.

At the convened meeting of the ACUC on April 28, 2022, the committee was presented with a summary of the incident. There was vigorous discussion of the transfer process and the need to encourage and make collaborations with VMS accessible while trying to reduce the administrative burden. In addition, the committee deliberated over whether the incident was a non-compliance and reportable. The ACUC voted 6-3 that the incident is reportable to OLAW based upon the OLAW guidance example of reportable situation "conduct of animal-related activities without appropriate IACUC review and approval, failure to adhere to IACUC-approved protocols, or implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by PHS Policy IV.B.7."

The ACUC recommends:

- Re-training of the transfer and ACUC approval requirements for the involved personnel.

- Evaluation of the transfer policy regarding collaborations with VMS to simplify the process. Moving forward, collaborations that require transfer to ASP 85-06 for refinement or development of surgical and/or technical procedures, per the approved ASP, will be coordinated through an email to the ACUC office and ACUC Chair. Temporary transfers to 85-06 will not require cage card reprinting.
- Inclusion of the ACUC Office when Experimental Summary Sheets (ESS) are submitted to ARS detailing collaborations or pilots with VMS to ensure appropriate ACUC approvals are in place.

The ACUC feels these actions will prevent the occurrence of a similar incident in the future.

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Paul Wade
Chair, ACUC, NIEHS, NIH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 18, 2022 7:09 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIEHS 16-22))

Thank you for this report. 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: Monday, May 16, 2022 3:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIEHS 16-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute of Environmental Health Sciences (NIEHS) ACUC address an animal incident involving the conduct of a surgical procedure on six mice which had not been appropriately transferred to a training protocol. Also, the surgical procedure was not described or listed in an ACUC approved animal study proposal.. The event was first reported to the NIH Office of Animal Care and Use by the NIEHS ACUC Chairman on April 18, 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** |