



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 20892-6910
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) 402-7065

July 18, 2018

Re: Animal Welfare Assurance
A3426-01 [OLAW Case W]

Grace Fisher-Adams, PhD, JD
Director, Office of Research Compliance
California Institute of Technology
1200 E. California Boulevard, MC B110-21
Pasadena, CA 91125

Dear Dr. Fisher-Adams,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 12, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the California Institute of Technology, following up on an initial June 8, 2018 telephone notification. According to the information provided, OLAW understands that an unapproved non-pharmaceutical grade anesthetic was administered to six individual mice for terminal procedures on six separate experiments. Although the associated animal activities were PHS funded, all expenditures charged against the grant during the periods of noncompliance were transferred to non-federal accounts and the funding agency has been notified of the noncompliance.

The corrective actions consisted of the Principal Investigator discontinuing the use of the anesthetic until the IACUC has approved the amendment to include the use of the non-pharmaceutical grade anesthetic and the responsible researcher retraining on responsibilities when working with animals and carefully reviewing the protocol with veterinary personnel.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair
Director, Office of Laboratory Animal Resources



Office of Research Compliance

Grace Fisher-Adams, PhD, JD
Director, Institutional Official
1200 E. California Blvd., MC B110-31
Pasadena, CA 91125
(626) 395-2907
Grace.Fisher-Adams@caltech.edu

July 12, 2018

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

The California Institute of Technology (Caltech), in accordance with Assurance A3426-0 and PHS Policy IV.F.3., provides this report of a protocol non-compliance regarding an incident where a non-pharmaceutical grade anesthetic was used in mice that was not approved by the IACUC. The incident was first reported to Dr. Neera Gopee, OLAW, on June 8, 2018 by Dr. Karen Lencioni, Caltech's Director of the Office of Laboratory Animal Resources.

On June 4, 2018, the Office of Research Compliance received information that, during an IACUC inspection, a researcher was found using a non-pharmaceutical grade anesthetic in mice that was not included on the laboratory's approved IACUC protocol. The researcher was asked to stop all such experiments and submit an amendment to the IACUC immediately. The IACUC Chair and the Institutional Official were notified after the inspection and the IACUC was notified of the possible non-compliance at its meeting on June 12, 2018. Representatives from the IACUC and Institutional Official met with the researcher and the PI on June 18, 2018, to assess the situation. Upon further investigation, it was discovered that the unapproved anesthetic was used in six separate experiments involving six individual mice on March 11, March 16, March 20, April 28, May 2, and May 14, 2018. Each of these procedures was a terminal procedure and each animal was euthanized pursuant to the approved IACUC protocol.

A review of billing records showed that a portion of the direct costs associated with the care of the affected animals was charged to NIH Grant U01-NS09057. These costs have been reallocated to, and paid from, nonfederal sources. NIH funding components affected have been notified of the situation.

To address the situation, the researcher has discontinued the use of the non-pharmaceutical grade anesthetic and has submitted an amendment to the IACUC protocol requesting an exception to continue to use this anesthetic. Further, the researcher has carefully reviewed the protocol with veterinary staff and has been retrained with regard to the researcher's obligations when working with animals.

At its meeting on July 10, 2018, the IACUC reviewed the corrective actions taken and is satisfied that such an incident will not occur again.

Caltech is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Richard Andersen, Ph.D., IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

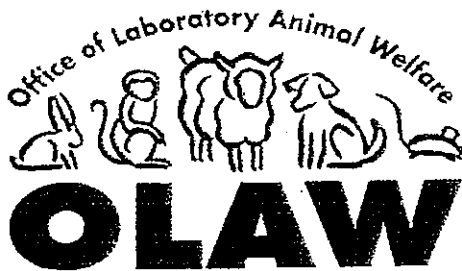
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Grace Fisher-Adams, PhD, JD
Director of Research Compliance
Institutional Official

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Initial Report of Noncompliance

By: Neera Ghee

Date: 06-08-18

Time: 2:35pm

Name of Person reporting: Karen Lencion

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Caltech

Assurance number: D16-00266 (A3426-01)

Did incident involve PHS funded activity? unknown

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

unapproved use of an anesthetic in mice. No animal welfare issues to report.

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

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Case # _____