



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

June 5, 2019

Re: Animal Welfare Assurance
A3426-01 [OLAW Case 1A]

Dr. Fisher-Adams
Director, Office of Research Compliance
California Institute of Technology
1200 E. California Boulevard, MC 104-010
Pasadena, CA 91125

Dear Dr. Fisher-Adams,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 3, 2019 letter reporting the suspension of a protocol at the California Institute of Technology, following up on an initial telephone report on May 17, 2019. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after a graduate student was exposed to rhesus monkey fluids by failing to wear all required personal protective equipment. The same incident had occurred previously. There were also instances of protocol noncompliance which had already been reported to OLAW.

In addition to suspending the protocol, the IACUC has required a corrective action plan from the laboratory which is to include retraining the staff in correct animal use, safety, and laboratory management. All experimental animal activities have stopped and the monkeys have been transferred to a holding protocol under the veterinary staff. The funding component and USDA have been notified and no costs will be charged to the grant during the suspension.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Note that NIH does allow expenditure of grant funds for animal maintenance during a period of suspension if approved by the funding component. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html> Please inform OLAW if any additional actions are required for the laboratory (e.g., enhanced post-approval monitoring) or if the status of suspension changes (e.g., termination). Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



Office of Research Compliance

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

June 3, 2019

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, in accordance with its Assurance D16-00266 (A3426-01) and PHS Policy IV.F.3., provides this report of an IACUC protocol suspension following an occupational health exposure preceded by a previous exposure and a series of protocol non-compliance events. Importantly, the non-compliances, including some that were previously reported to OLAW, did not result in any significant adverse animal welfare issues. The suspension was first reported to Dr. Axel Wolff, OLAW, on May 17, 2019, via a telephone call from Karen Lencioni, DVM, DACLAM, and Director of Office of Laboratory Animal Resources.

On May 1, 2019, the Office of Research Compliance received information from the Attending Veterinarian that a graduate student, working in a non-human primate laboratory was exposed to animal fluids as a result of failing to wear all appropriate personal protective equipment. This was the second such incident in less than a year. These occupational health exposures, in addition to several minor non-compliance events over the past year, compelled the IACUC to carefully reexamine the activities in this lab under IACUC Protocol #1574-19. At its regular convened meeting on May 14, 2019, the IACUC voted to suspend the protocol. The length of the suspension is dependent upon the length of time needed for the laboratory to implement an IACUC-prescribed corrective action plan.

A subcommittee of the IACUC met on May 16, 2019, to set forth the parameters of the suspension and to develop the action plan. The suspension was made effective May 17, 2019 and will remain in effect until all of the conditions of the action plan are satisfied. The action plan includes plans for retraining laboratory members in animal use, safety and laboratory management. During the suspension, all animal experimentation in the laboratory performed under Protocol #1574-19, has ceased and the animals have been administratively transferred to a veterinary holding protocol. All care during the suspension period is either being provided directly from the veterinary staff or closely directed and/or overseen by the veterinary staff.

A review of billing records showed that a portion of the direct costs associated with the care of the affected animals have been charged to NIH Grant R01MH111425, NIH Grant DPNS083063, and several non-federal sponsors. During the suspension period, all costs shall be allocated, invoiced to, and paid from nonfederal sources. USDA and all funding components affected will be notified about the suspension, as appropriate.

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 me or Richard Andersen, Ph.D., IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, June 5, 2019 6:19 AM
To: IACUC (IACUC@caltech.edu)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: FW: Caltech Report of Incident
Attachments: OLAW report 1574 Suspension GFA Final.pdf

Thank you for this report. I will send a response soon.

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

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, June 4, 2019 8:37 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: FW: Caltech Report of Incident

One more that mentions a conversation with you. I did not acknowledge. Brent

Brent C. Morse, DVM, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: IACUC <IACUC@caltech.edu>
Sent: Monday, June 03, 2019 2:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Fisher-Adams, Grace C. <Grace.Fisher-Adams@caltech.edu>
Subject: Caltech Report of Incident

To Whom it May Concern,

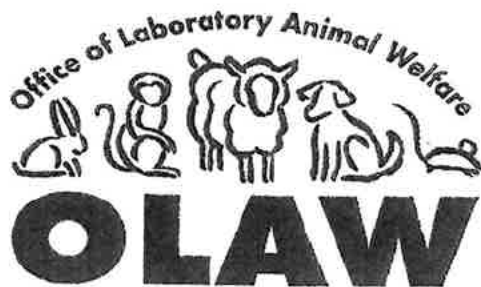
Attached is a report of an animal welfare incident and subsequent IACUC protocol suspension. The incident was discussed between Dr. Axel Wolff and Dr. Karen Lencioni on April 17, 2019.

If there are any questions or concerns regarding the attached follow-up report, please let me know.

Thank you,

(b) (6)

(b) (6)



Initial Report of Noncompliance

By: *aw*

Date: *5/17/19*

Time: *1:00*

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: *California Institute of Technology*

Assurance number: *A3426*

Did incident involve PHS funded activity? *yes*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Exposures to aerosols several times because not wearing PPE

Species involved: *Primates*

Personnel involved:

Dates and times:

Animal deaths:

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

Suspect protocol. Will report to funding component

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____