



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) 480-3387

July 13, 2021

Re: Animal Welfare Assurance
A3539-01 [OLAW Case 1F]

Dr. Martin Hetzer
Vice President and Chief Scientific Officer
The Salk Institute for Biological Studies
10010 North Torrey Pines Road
La Jolla, CA 92037-1099

Dear Dr. Hetzer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 8, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Salk Institute for Biological Studies. Your letter supplements the information provided in a preliminary telephone report made on April 2, 2021. According to the information provided, OLAW understands that there was an inadvertent delay in providing post-operative analgesics to a cynomolgus macaque. The animal received pre-and intra-operative analgesia and the animals recovered as expected with no clinical signs of increased pain. The error was recognized 11 hours after surgical recovery and the analgesic was administered upon discovery of the error. The study is PHS funded.

As a corrective measure, program veterinarians retrained laboratory members on protocol and regulatory expectations along with multiple checks and balances during the post-operative recovery timeframe. The individual responsible for collecting and administering the analgesic will have a conversation with veterinary services staff regarding the location of the analgesic, tagging the syringe with a special label and two individuals will be required to read the syringe label and visualize the administration of the analgesic to the animal.

OLAW appreciates the prompt consideration of this matter by the Salk Institute for Biological Studies which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S
Date: 2021.07.13 15:21:40
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

CC: IACUC contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations, USDA

April 8th, 2021

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

Dear Dr. Wolff:

I wish to report an incident from the Salk Institute's Animal Care and Use Committee (Salk IACUC; Assurance # A3539-01, NIH/NIMH Grant UG3MH123394). There was a miscommunication between two lab members leading to an inadvertent and accidental delay in administration of a post-operative analgesic to a cynomolgus macaque. The animal did receive pre- and intra-operative analgesics, and there was no notable effect to the animal's recovery (the animal recovered as expected with no notable clinical signs of increased pain). As soon as the error was recognized (approximately 11 hours after recovery from surgery), the animal was administered the analgesic.

In order to ensure this doesn't happen again, program veterinarians retrained the lab members on protocol and regulatory expectations and discussed multiple steps to ensure checks and balances during the post-operative recovery window (the individual responsible for collecting and administering the injection will have a direct conversation with the veterinary services staff regarding the location of the analgesic, the analgesic syringe will be tagged with a special colored tape, and at least two pairs of eyes will be required to read the syringe label and visualize the injection). All individuals involved have every intention of ensuring this doesn't happen again, and we fully expect these extra steps will resolve the issue.

The Salk IACUC was quickly informed of the incident and voted that appropriate post-incident steps had been taken. Please be assured that the Salk Institute takes this matter very seriously and remains committed to protecting animal welfare and maintaining full compliance with federal and state regulations and requirements. In the event you have any questions regarding this report, please contact the IACUC Chair by emailing iacuc@salk.edu.

Thank you for your consideration in these matters.

Sincerely,

(b) (6)

Martin Hetzer, PhD
Vice President/CSO
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 9, 2021 7:48 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Salk Institute reportable incident

Thank you for this report, (b) (6) We will send a response soon. Note that OLAW's address changed some time ago and is as follows:
6700B Rockledge Dr. Suite 2500
Bethesda, MD 20892

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

From: (b) (6)
Sent: Thursday, April 8, 2021 3:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Martin Hetzer <hetzer@salk.edu>; (b) (6)
Subject: Salk Institute reportable incident

Good afternoon,

Attached please find the letter describing a reportable incident that occurred at our institution. Salk's Senior Director of Animal Resources, Trinka Adamson, and Institutional Official, Martin Hetzer, are cc'd on this email.

Please feel free to contact us with any questions or concerns.

Best regards,
(b) (6) on behalf of Martin Hetzer

(b) (6)



3539-1F

Initial Report of Noncompliance

By: (b) (6)

Date: 4/2/21

Time: 11:45

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Salk Institute

Assurance number: A3539

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Monkey didn't get long acting analgesic as required.
Monkey didn't seem to be in extra distress. Human error.*

Species involved: Macaque

Personnel involved: _____

Dates and times: _____

Animal deaths: _____

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

Have next day - SR Buprenorphine

Counsel staff, retrain. Have more people read syringe label.

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____