



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

January 24, 2020

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

Dr. Martin Hetzer
Vice President, 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 January 13, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Salk Institute.

According to the information provided, this Office understands that the Salk Institute Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: 5 cages of mice found with no feeder or food present on November 21, 2019. Investigation by the Research Compliance Analyst (RCA) revealed the mice were being fasted for 24h, bled for blood analysis, and then imaged in an MRI machine. It was determined that the 24h fasting and MRI procedures were not approved on the protocol. Food was provided to all cages and lab staff were instructed to cease research involving these procedures immediately. The IACUC convened a meeting and agreed to report the incident to OLAW and implement the following measures listed below.

- 1) The IACUC Chair and attending veterinarian met with the PI and researcher and requested submission of an amendment to add fasting and MRI for IACUC review.
- 2) The researcher's facility access was inactivated for one month. The researcher will be retrained on IACUC policies and expectations regarding reviewing and understanding the lab's approved protocol(s) before performing any procedures.
- 3) The lab manager was retrained on IACUC protocol review and approval processes and has committed to ensuring the lab members will be more proactive in reviewing their animal use protocols.
- 4) IACUC staff and RCA will provide retraining on IACUC policies and expectations to all personnel in the lab.

The lab has agreed to all corrective actions and are willing to acquire additional trainings to maintain compliance. Also, the RCA will continue to monitor the lab's research practices to evaluate efficacy of corrective actions implemented.

Based on its assessment of this explanation, OLAW understands that the Salk Institute has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



A3539-1C
No open cases
Salk Institute for Biological Studies
10010 N Torrey Pines Rd
La Jolla, California 92037

PH (858) 453-4100 x 1318
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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:

The Salk Institute, in accordance with the reporting requirements as defined by PHS Policy IV.F.3 and Assurance A3539-01, hereby communicates the following incident pertaining to the NIH grant CA197687.

On 11/21/19, the IACUC office was notified of 5 cages of mice with no feeder or food by the animal resources department. Further investigation by the Research Compliance Analyst (RCA) revealed that mice were being fasted for 24 hours, bled for blood analysis, and then imaged in an MRI machine. Of these procedures, fasting for 24 hours and MRIs were not approved on the protocol. In consulting with the IACUC Chair and Attending Veterinarian (AV), food was provided to all cages and lab staff were instructed to stop research involving these procedures immediately.

The IACUC immediately convened a meeting in order to address this noncompliance and agreed to report this incident to OLAW as well as implement the following measures:

1. The IACUC Chair and AV met with the PI and noncompliant researcher and requested immediate submission of an amendment to add fasting and MRI for IACUC review.
2. The researcher's facility access has been inactivated for a month; the researcher will be retrained on IACUC policies and expectations regarding reviewing and understanding the lab's approved protocol/s before performing any procedures.
3. The lab manager has been re-trained on IACUC protocol review and approval processes and has committed to ensuring that lab members will be more proactive in reviewing their animal use protocols.
4. The IACUC Staff and RCA will provide a retraining on IACUC policies and expectations to all personnel in the lab.

The lab has acknowledged this oversight, agreed to all corrective actions items and are willing to acquire any additional trainings necessary to maintain compliance. Additionally, the RCA will continue to monitor the lab's research practices to evaluate efficacy of the corrective actions implemented.

The Salk Institute is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW. In the event you have any questions regarding this report, please contact Ed Callaway Ph.D., IACUC Chair at (b) (6)

(b) (6)

Thank you for your consideration in these matters.

Sincerely,

 (b) (6)

Martin Hetzer
Vice President, Chief Science Officer
Institutional Official, The Salk Institute for Biological Studies

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 14, 2020 8:33 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Martin Hetzer; (b) (6)
Subject: RE: Incident Reports of Non-compliance

Thank you for submitting these reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

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

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From: (b) (6)
Sent: Monday, January 13, 2020 2:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Martin Hetzer <hetzer@salk.edu>; (b) (6)
Subject: Incident Reports of Non-compliance

Good afternoon,

Attached please find the three letters describing incidents of non-compliance that occurred at our institution. Our (b) (6) 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) for Martin Hetzer

(b) (6)