



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 1B]

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: unapproved surgical procedures (ovariectomy) in 5 mice. The Research Compliance Analyst (RCA) discovered this incident by identifying post-operative logs in the animal facility maintained by a lab. The logs indicated the animals were recovering well and did not present any welfare concerns. Investigation revealed the ovariectomy procedure had been submitted as an amendment for review, and miscommunication led the researcher to believe the procedure had been approved, which it had not. The amendment was approved on November 19, 2019 and no further surgeries were conducted during the interim between discovery of noncompliance and approval of the protocol. The researcher and lab manager discussed the incident with RCA and IACUC staff. They indicated they would verify approvals of procedures prior to performing subsequent procedures. The incident was discussed at a convened IACUC meeting and the committee unanimously voted to report it. The IACUC staff retrained the lab manager and researcher on IACUC protocol review and approval processes. It is noted that this project is PHS funded.

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



A3539-1B
No open cases

Salk Institute for Biological Studies
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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 11/13/19, the Research Compliance Analyst (RCA) identified post-operative logs in the animal facility maintained by a laboratory for an unapproved surgical procedure, ovariectomy of mice. The procedure was performed on (5) mice in a single session. The logs indicated that the animals were recovering well and did not present any welfare concerns. Investigation of the incident revealed that the noncompliance was a result of miscommunication between the laboratory manager and the researcher performing the procedure. The ovariectomy procedure had recently submitted as an amendment for review by designated member review, however, an unfortunate miscommunication led the researcher to believe the procedure was approved while it was not. The procedure was subsequently approved after review on 11/19/19. No further ovariectomies were conducting during the interim between discovery of noncompliance and approval of the protocol.

The researcher and lab manager were met by the RCA and the IACUC staff to discuss the incident. Both acknowledged misunderstanding review timelines and indicated that they would verify approvals of procedures prior to performing subsequent procedures. The IACUC Chair and Attending Veterinarian were immediately contacted, the incident was discussed at a convened IACUC meeting and the committee unanimously voted to report it. The IACUC staff re-trained the lab manager and researcher on IACUC protocol review and approval processes.

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

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)