



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

April 1, 2020

Re: Animal Welfare Assurance
A3500-01 [OLAW Case Q]

Dr. Mridul Gautam
Vice President for Research
and Innovation
University of Nevada-Reno
1664 N. Virginia St. – MS 326
Reno, NV 89557

Dear Dr. Gautam,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 30, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Nevada- Reno, following up on an initial telephone report on March 26, 2020. According to the information provided, OLAW understands that 43 cages of mice were housed in the vivarium after the protocol had expired. No experimental activities had been conducted during the lapse and the PHS grant was not charged for animal care costs.

The initial corrective action consisted of transferring the mice to a holding protocol. The Principal Investigator (PI) was directed to stop all research activities until the protocol was approved. The protocol was subsequently approved by the Institutional Animal Care and Use Committee (IACUC) using designated member review. The IACUC database is being converted to a new software package which will allow flagging of expiring protocols to provide timely notification to the PI.

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.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Division of Compliance Oversight

cc: IACUC Chair



University of Nevada, Reno
Research & Innovation

March 30, 2020

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892
Email: olawdco@mail.nih.gov

RE: Assurance D16-00311 (#A3500-01) – University of Nevada, Reno (UNR)

Dear Dr. Morse:

This letter is the final report to inform you of a self-identified non-compliance event that was reported to the UNR IACUC Chair on March 24, 2020 and described in a preliminary report made via telephone by the UNR Attending Veterinarian to your office on March 26, 2020. It involves a finding of an activity involving laboratory mice which, for a recent limited period of time, was non-compliant with PHS Policy and with the *Guide for the Care and Use of Laboratory Animals* (NRC, 2011) concerning the use of our PHS Award 5R01-DK-091336-07. A sub-committee consisting of three IACUC members met on March 26, 2020 to discuss the matter in detail. The event involved the ongoing housing of 43 cages of laboratory mice in one of the centralized animal facilities subsequent to the 3-year expiration of the protocol as of February 15, 2020. The IACUC Administrator noticed this protocol still in draft phase within the software after it had already lapsed. The subcommittee was informed that none of the animals had been used for experimentation during that period of lapse. A de novo protocol had been prepared within the UNR's electronic protocol database system, but due to illness of the PI and travel by his key staff members, it had not been electronically submitted. No weaning of mouse cages or other animal husbandry activity had occurred when this mistake was identified, and thus the colony management system also did not notice this error during the affected window of time. Furthermore, no billing for animal care costs to the involved PHS award has occurred. This colony of laboratory mice is maintained by the Office of Animal Resources on behalf of the PI, so the assessment of the circumstances of this problem was deemed to be complete. Mice continued to be held within the centralized animal facilities under the approved provisions of the Animal Holding Protocol, whereby the Institution's Attending Veterinarian is the PI. There were no significant impacts to the PHS Award due to this short period of IACUC protocol lapse.

The subcommittee's recommendations include completion of the following corrective actions:

- The PI was asked to stop any research that requires use of these mice until the protocol has been reviewed and approved in writing by the IACUC for its de novo 3-year renewal.
- No charges to the corresponding PHS Award are allowed to occur until the protocol has been re-approved, and all animal care charges during the period of lapse must be charged to a departmental account not associated with any PHS or NSF or VA award.
- In accordance with its operating procedures, the IACUC approved a Designated Member Review process for the protocol to reduce the period of lapsed time between approvals.
- The DMR process resulted in re-approval of the protocol for another 3-year period today.
- The UNR was already in process of converting its IACUC database to a different software package when this event occurred; the new software package has improved reporting capabilities which will greatly help us in providing advance notifications regarding active protocols due to expire well in advance of another possible lapse.
- All of these issues and findings will be discussed during the next regularly scheduled IACUC meeting to occur on April 15, 2020.

We consider that this issue of non-compliance has now been fully resolved, but please do not hesitate to contact me if you have any questions or concerns. The UNR is fully committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Mridul Gautam, Ph.D.
Institutional Official
Vice President for Research & Innovation
Tel. (b) (6)
Email: mgautam@unr.edu

CC: Mike B. Teglas DVM, Ph.D. - Institutional Animal Care and Use Committee Chair
Ben Weigler, DVM, MPH, Ph.D., DACLAM, DACVPM – Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 1, 2020 8:01 AM
To: Benjamin J Weigler
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00311 Report

Thank you for this report, Dr. Weigler. We will respond soon.
Axel Wolff

From: Benjamin J Weigler <bweigler@unr.edu>
Sent: Tuesday, March 31, 2020 3:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Mridul Gautam <mgautam@unr.edu>; Teglas, Michael <mteglas@cabnr.unr.edu>; (b) (6)
(b) (6)
Subject: D16-00311 Report

Dear OLAW Division of Compliance Oversight –

Please see the attached letter from our Institutional Official representing our final report to you. Many thanks,

Ben

*Benjamin J. Weigler, DVM, MPH, Ph.D., DACLAM, DACVPM
Director & Attending Veterinarian - Animal Resources
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University of Nevada, Reno
Research & Innovation

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Initial Report of Noncompliance

By: (b) (6)

Date: 3/26/20

Time: 8:40 PM Via email

Name of Person reporting: Ben Weigler, AV

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Univ Nevada-Reno

Assurance number: A3500

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Protocol approved + activities continued - breeding, euthanasia, tissue harvest. No problems with mice. PI in hospital.

Species involved: Mice

Personnel involved:

Dates and times:

Animal deaths:

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

New protocol software system being put in place

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____