



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

May 28, 2019

Re: Animal Welfare Assurance
A3240-01 [OLAW Case F]

Dr. Randal Hewes
Dean of the Graduate College
University of Oklahoma
104 Parrington Oval, Room 104F
Norman, OK 73019

Dear Dr. Hewes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 16, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Oklahoma, following up on an initial telephone report on April 12, 2019. According to the information provided, OLAW understands that a rat exhibited post-surgical hind limb paralysis. The Attending Veterinarian and Principal Investigator (PI) determined that laboratory member who had performed the surgery was not qualified, had not conducted pre-surgical planning with the PI, had substituted a rat for a mouse which was the species approved in the protocol and had used a rat from another protocol. There was ineffective communication between the PI and staff, the laboratory staff had not consulted the veterinarians for assistance, and the laboratory staff had not completed the mandatory surgical training.

The corrective actions consisted of euthanizing the rat and having the Institutional Official suspend the protocol. The Institutional Animal Care and Use Committee (IACUC) required the PI to implement a communication system for animal issues and to ensure completion of all required training by staff prior to conducting surgery. The individual who had conducted the rat surgery had their animal use privileges permanently revoked. IACUC policies were modified to require completion of all required training of staff prior to protocol approval, to require assessment of competency by a veterinarian of any staff member planning to conduct their first surgery, and to require veterinary technical assistance during surgeries when deemed necessary by the IACUC.

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. Unless informed to the contrary, OLAW assumes that the IACUC reinstated the protocol following full implementation of the corrective actions. 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



The UNIVERSITY of OKLAHOMA

Office of the Vice President for Research

May 16, 2019

Brent Morse, 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. Morse:

The University of Oklahoma, in accordance with Assurance **A3240-01** and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident involving a surgical procedure on a rat. The protocol was internally funded by the institution. This incident was reported to Dr. Axel Wolff via telephone on April 12, 2019.

On April 10, 2019, the institution's Attending Veterinarian (AV) was contacted by the Facility Manager regarding a post-surgery rat that appeared to be hind-limb paralyzed, an unanticipated outcome for the protocol under which the surgery was performed. The AV assessed the animal, determined the animal was experiencing hind-limb paralysis, and performed euthanasia.

In reviewing the incident, the AV and the Principal Investigator (PI) agreed that the research affiliate performing the surgery was not qualified to perform the procedure. Additionally, the PI had not been advised that the affiliate was going to perform the surgery, so no PI-facilitated pre-surgical planning had occurred. The affiliate substituted a rat for the protocol approved animal of mouse. Finally, the animal that was used was from another of the PI's protocol. The incident was communicated to the Institutional Official, who immediately suspended the protocol until such time that the IACUC could convene and review the situation.

On April 22, 2019, the IACUC met in formal session to review the incident, determine reportability, and define necessary corrective measures. The IACUC determined the following represented instances of non-compliance occurred and notice to OLAW was appropriate:

- The PI did not have an effective communication process in place with the laboratory staff.
- The laboratory staff did not seek veterinary assistance with peri-operative support activities that they were not sufficiently experienced with, and
- The laboratory staff had not completed the IACUC-mandated surgical skills training prior to initiation of the surgery.

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The IACUC determined the following corrective measures were necessary:

1. Specific:
 - a. Suspension of the current protocol to provide the PI the time to:
 - i. build an effective communication process for animal care and use activities,
 - ii. make training available to research staff (including himself) by the veterinary staff, and
 - iii. ensure all staff on a research study have completed the IACUC-mandated surgical skills training before reviewing a new protocol.
 - b. Permanent removal of animal access privileges for the affiliate performing the procedure.
2. Generalized:
 - a. revision of the IACUC policies on protocol review and performance to require that staff have completed all required training prior to protocol approval,
 - b. establish an IACUC policy that a staff member's 'first surgery' must be performed in the presence of the institution's veterinarian to assure surgeon competency, and
 - c. establish an IACUC policy requiring veterinary technician surgical support for select laboratories or activities, when determined necessary by the IACUC during protocol review.

The IACUC reviewed a letter from the PI, in which he took responsibility for the noncompliance. At its meeting on May 9, 2019, the IACUC reviewed and accepted the corrective action plan as submitted by the PI.

The IACUC concluded its deliberations with a decision that this was an isolated incident and not a programmatic failure. It also recognized this incident as an opportunity to refine programmatic processes to mitigate or prevent a similar future occurrence.

The University of Oklahoma is committed to protecting the welfare of animals used in research and appreciates the oversight provided by OLAW in this regard. Should you have any questions regarding this report, please contact Eli Bridge, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Randall S. Hewes, Ph.D.
Interim Vice President for Research
Institutional Official

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, May 20, 2019 12:26 PM
To: Preno, Alisha (HSC)
Cc: Hewes, Randall S.
Subject: RE: Report - The University of Oklahoma- Norman campus

Thank you for providing this final report Dr. Preno. We will send an official response soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Preno, Alisha (HSC) [mailto:Alisha-Preno@ouhsc.edu]
Sent: Thursday, May 16, 2019 4:28 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Hewes, Randall S. <hewes@ou.edu>
Subject: Report - The University of Oklahoma- Norman campus

Good afternoon Dr. Morse,

I have attached a report to this e-mail which closes the circle on an event that was reported by telephone from the University of Oklahoma- Norman campus. Please let me know if you have any questions.

Thank you,

Alisha

Alisha N. Preno, DVM
Attending Veterinarian
Director, Laboratory Animal Resources
The University of Oklahoma - Norman



Initial Report of Noncompliance

By: *aw*Date: *4/12/19*Time: *12:30*Name of Person reporting: *(b) (6)*Telephone #: *(b) (6)*

Fax #:

Email:

*Allen Perino*Name of Institution: *U of Oklahoma Norman Campus*Assurance number: *A3240*Did incident involve PHS funded activity? *?*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*PI "spayed" a male rat, rats not on protocol*Species involved: *Rat*

Personnel involved:

Dates and times:

Animal deaths:

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

IO suspended study

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____