



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

February 11, 2020

Re: Animal Welfare Assurance
A3774-01 [OLAW Case B]

Brad R. Woods, Ph.D.
Executive Director, Office of Research Integrity
University of Nevada – Las Vegas
4505 South Maryland Parkway-Box451047
Las Vegas, Nevada 89154

Dear Dr. Woods,

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 University of Nevada, Las Vegas as a follow-up to the preliminary report submitted November 22, 2019. According to the information provided, OLAW understands that on November 21, 2019, the IACUC was informed that an animal care staff member discovered a mouse with a suture on its side which is unusual for the colony. IACUC records and associated approved protocol had no approved surgical procedures listed. The principal investigator (PI) was contacted and all work except husbandry and care was immediately halted. The study is PHS funded and the PI was directed to report the non-compliance to the project sponsor immediately.

As a corrective measure, the following actions were implemented by the IACUC:

- The undergraduate student who performed the surgery was prohibited from accessing live animals until she retakes the CITI training and completes the initial 3 hour in-person training required of all the PI's staff.
- All approved future surgeries will include observation of the initial surgery by an experienced surgeon or someone approved by the IACUC Chair and University Veterinarian. If the observer believes additional training is necessary, the IACUC chair will be informed and prompted to review the recommendation and implement additional training as needed.
- The PI was directed to attend six IACUC monthly meetings in 2020 to become familiar with action and responsibilities of the IACUC.
- The PI was directed to post a one-page summary of allowable (approved) procedures in the mouse room and distribute this information to the employees that are approved to work with animals.
- A copy of the Guide for Care and Use of Laboratory Animals was provided to the PI and the was PI directed to summarize pertinent sections in a three hour in-person training session to their staff in the Spring and Fall 2020 semesters. Additionally, all workers listed on the approved protocol from the laboratory are mandated to attend one or both sessions. This training is intended to ensure staff are aware of animal welfare and responsible animal care.

OLAW appreciates the prompt consideration of this matter by the University of Nevada, Las Vegas which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW understands that one mouse was involved in this non-compliance event with no adverse animal health outcomes (e.g. illness, death) reported and therefore OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. Please contact us directly if there are further details on the non-compliance events that have not been previously included in your report. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

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

cc: IACUC Contact

Final

UNLV | Office of RESEARCH INTEGRITY

January 13, 2020

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:

In accordance with Assurance A3774-01 and PHS Policy IV.F.3, I am writing to you to submit a final report related to mouse survival surgeries (total of 3 mice) without IACUC approval.

As a reminder, on Thursday, November 21, 2019, the IACUC was informed that an animal care staff member discovered a mouse with a suture on its side and noted this as unusual for this colony. IACUC records were reviewed and the associated IACUC approved protocol has no approved surgical procedures. The UNLV IACUC immediately contacted the Principal Investigator (PI) and noted all work except for husbandry and care be immediately halted until an investigation was completed.

This project is funded through the National Institutes of Health. The PI was directed to report this to the sponsor immediately.

After meeting with the involved parties to better understand the timeline and processes leading up to the surgeries, the IACUC initiated the following corrective actions:

- 1) A copy of the Guide for the Care and Use of Laboratory Animals was provided to the PI. The PI was directed to summarize pertinent sections in three-hour in-person training sessions to their staff in the Spring and Fall semesters of 2020. Additionally, all workers listed on the approved protocol from the laboratory were mandated to attend one or both sessions. This training is intended to ensure staff are aware of animal welfare and responsible animal care.
- 2) The PI was directed to post a one page summary of allowable procedures in the mouse room and distribute this information to the employees that are approved to work with animals.
- 3) The PI was directed to attend six IACUC monthly meetings in 2020 to become better familiarized with the actions and responsibilities of the IACUC.
- 4) All approved future surgeries will include observation of the initial surgery by an experienced surgeon or someone approved by the IACUC Chair and University Veterinarian. If the observer believes additional training is necessary, he or she can inform the IACUC Chair, who will review the recommendation and implement additional training as necessary.

- 5) The undergraduate student who performed the surgical activities was prohibited from accessing live animals until she re-takes the online CITI training courses, provides evidence of completed training records of these courses, and completes the initial 3 hour in-person training required of all the PI's staff as noted above.

This non-compliance was determined to be a result of poor communication between a PI and his student as well as inadequate PI oversight. This was deemed to be an individual and isolated action (i.e., not systemic) and therefore the IACUC determined no additional actions beyond those outlined above were necessary.

Thank you for your review of this final report.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

(b) (6)

Brad R. Woods, Ph.D.
Executive Director, ORI
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 13, 2020 4:28 PM
To: Brad Woods; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Final Report--noncompliance

Thank you for providing this final report Dr. Woods. 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: Brad Woods [mailto:brad.woods@unlv.edu]
Sent: Monday, January 13, 2020 2:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Final Report--noncompliance
Importance: High

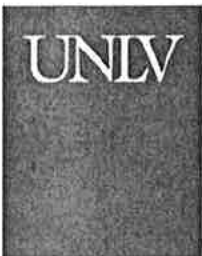
Dear Dr. Wolff,

Attached please find a final report of noncompliance. You were sent a preliminary report related to an incident of noncompliance on November 22, 2019.

Please contact me if you have any questions or concerns.

Thank you for your review and attention to this matter.

Sincerely,



Brad R. Woods, Ph.D.
Executive Director and Research Integrity Officer;
Institutional and Empowered Official;
Chair, Research Advisory Committee on Cannabis & Hemp
Office of Research Integrity
University of Nevada, Las Vegas



brad.woods@unlv.edu

Office: (b) (6)

Web

UNLV | Office of RESEARCH INTEGRITY

November 22, 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:

In accordance with Assurance A3774-01 and PHS Policy IV.F.3, I am writing to you to submit a preliminary report related to mouse survival surgeries (total of 3 mice) without IACUC approval. There were no mice deaths attributed to the surgeries. The IACUC was informed on Thursday, November 21, 2019, that an animal care staff member discovered a mouse with a suture on its side and noted this as unusual for this colony. IACUC records were reviewed and the associated IACUC approved protocol has no approved surgical procedures. The UNLV IACUC immediately contacted the Principal Investigator and noted all work except for husbandry and care be immediately halted until an investigation is completed.

This project is funded through the National Institutes of Health. We will require the PI report this to the sponsor immediately.

Thank you for your review of this report. I anticipate the final report will be sent to you within 60 calendar days.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

(b) (6)

Brad R. Woods, Ph.D.
Executive Director, ORI
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 25, 2019 6:27 AM
To: Brad Woods
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report--noncompliance

Thank you for this preliminary report, Dr. Woods. We will start a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

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

From: Brad Woods <brad.woods@unlv.edu>
Sent: Friday, November 22, 2019 3:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: [REDACTED] (b) (6)

Subject: Preliminary Report--noncompliance
Importance: High

Dear Dr. Morse,

Attached is a preliminary report based on an apparent instance of noncompliance.

Please contact me if you have any questions or concerns.

Thank you for your review and attention to this matter.

Sincerely,



Brad R. Woods, Ph.D.
Executive Director and Research Integrity Officer;
Institutional and Empowered Official;
Office of Research Integrity
University of Nevada, Las Vegas

brad.woods@unlv.edu
Office: [REDACTED] (b) (6)

Web

A3774-B

UNLV | Office of RESEARCH INTEGRITY

November 22, 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:

In accordance with Assurance A3774-01 and PHS Policy IV.F.3, I am writing to you to submit a preliminary report related to mouse survival surgeries (total of 3 mice) without IACUC approval. There were no mice deaths attributed to the surgeries. The IACUC was informed on Thursday, November 21, 2019, that an animal care staff member discovered a mouse with a suture on its side and noted this as unusual for this colony. IACUC records were reviewed and the associated IACUC approved protocol has no approved surgical procedures. The UNLV IACUC immediately contacted the Principal Investigator and noted all work except for husbandry and care be immediately halted until an investigation is completed.

This project is funded through the National Institutes of Health. We will require the PI report this to the sponsor immediately.

Thank you for your review of this report. I anticipate the final report will be sent to you within 60 calendar days. ←

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

(b) (6)

Brad R. Woods, Ph.D.
Executive Director, ORI
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 25, 2019 6:27 AM
To: Brad Woods
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report--noncompliance

Thank you for this preliminary report, Dr. Woods. We will start a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

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

From: Brad Woods <brad.woods@unlv.edu>
Sent: Friday, November 22, 2019 3:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)

Subject: Preliminary Report--noncompliance
Importance: High

Dear Dr. Morse,

Attached is a preliminary report based on an apparent instance of noncompliance.

Please contact me if you have any questions or concerns.

Thank you for your review and attention to this matter.

Sincerely,



Brad R. Woods, Ph.D.
Executive Director and Research Integrity Officer;
Institutional and Empowered Official;
Office of Research Integrity
University of Nevada, Las Vegas

brad.woods@unlv.edu
Office: [REDACTED] (b) (6)

Web