



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) 480-3377

February 18, 2020

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 6V]

Dr. David P. Norton
Vice President for Research
University of Florida
(b) (4) Grinter Hall
Gainesville, FL 32611-5500

Dear Dr. Norton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 2, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida.

According to the information provided, this Office understands that the University of Florida Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to IACUC-approved protocol; failure to provide analgesia during surgery; failure to maintain controlled substance records; and transferring of animals without IACUC approval. The final report states that on October 16, 2019 it was reported to the IACUC that mice had recovered briefly following a non-survival surgery. During the IACUC investigation on November 4, 2019 the following findings were discovered:

- The surgeon stated she obtained 8 mice without IACUC approval from other investigators to practice a tracheal cannulation surgery (note: only 4 mice were used).
- Animals did not receive analgesia and they were allowed to recover from surgery.
- Ketamine/xylazine anesthesia was used and no records were maintained for the ketamine usage.
- Surgical records were not being maintained and gas scavenging canisters were not being weighed as well.

The PI implemented the following corrective actions:

- PI has stopped all animal work since the incident.
- Personnel involved in the incident have been removed from the protocol and will not be reinstated.
- A new study coordinator has been named and is assisting the PI in resolving the compliance concerns and helping to identify/hire a new scientist.

The IACUC reviewed the incident on December 17, 2019 and determined it was reportable. The committee also requested that before resuming any animal work, all study personnel will take/re-take the following AALAS training:

- Working with the IACUC.
- Aseptic Technique for Rodent Survival Surgery.
- Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
- Working with the Laboratory Mouse.
- Pain Management in Laboratory Animals.

It is noted that this study was not supported by PHS funds. Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. 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

Office of the Vice President for Research

223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500
352-392-1582

January 2, 2020

Axel Wolff, 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. Wolff:

The University of Florida, in accordance with Assurance A3377-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident of failure to adhere to IACUC-approved protocol; failure to provide analgesia during surgery; failure to maintain controlled substance records; and transferring of animals without IACUC approval.

On October 16, 2019 it was reported to the IACUC that mice had been allowed to recover briefly following a non-survival surgery. There was additional concern over the animal wellbeing because the person who reported the incident observed the mice gasping for air.

On November 4, 2019 during the IACUC investigation the surgeon stated that she obtained 8 animals without IACUC approval from other investigators to practice a tracheal cannulation surgery. Subsequently only 4 mice were used. The practice surgeries occurred between September 5, 2019 and September 16, 2019. Animals did not receive analgesia but were allowed to recover following surgery. Ketamine/Xylazine were used as anesthesia, however no records were maintained for the ketamine usage. In addition, surgical records were not being maintained and the gas scavenging canisters were not being weighed.

The PI implemented the following corrective actions:

- 1) Since the incident occurred the PI has stopped all animal work.
- 2) Personnel involved in the incident have been removed from the protocol and will not be reinstated.
- 3) A new study coordinator has been named and is assisting the PI in resolving the compliance concerns and helping to identify/hire a new scientist.

On December 17, 2019 the IACUC reviewed the incident and determined that it was a reportable noncompliance. The IACUC requested the following additional corrective actions:

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- 1) Before resuming any animal work, all study personnel will take/re-take the following training:
 - a. AALAS-04155 Working with the IACUC
 - b. AALAS-02514 Aseptic Technique for Rodent Survival Surgery
 - c. AALAS-00245 Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
 - d. AALAS-02451 Working with the Laboratory Mouse
 - e. AALAS-03982 Pain Management in Laboratory Animals

This study is not PHS funded.

The University of Florida is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Daniel R. Brown, Ph.D., IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

David Norton, Ph.D.
Vice President for Research
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 14, 2020 7:57 AM
To: Mahoney,Michael P; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable noncompliance (2019Dec02 - 00659309)

Thank you for submitting this report Mr. Mahoney. 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: Mahoney,Michael P [mailto:mmahoney@ufl.edu]
Sent: Monday, January 13, 2020 12:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable noncompliance (2019Dec02 - 00659309)

Dr. Morse,

I am sending the attached report of noncompliance from the University of Florida. UF did not send a preliminary report for this event.

The protocol involved in this noncompliance is not funded by PHS.

Please acknowledge receipt and let me know if you have any issues.

-Michael

Michael Mahoney
Director of Research Operations and Services
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PO Box 115500 | Gainesville, FL 32611-5500
PH: (b) (6) <http://research.ufl.edu/research-operations-services.html>

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