



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

April 17, 2020

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 7E]

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

Dear Dr. Norton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 12, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida. This letter had not been preceded by a preliminary report to OLAW.

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 provide animals analgesia as outlined in the IACUC protocol. The final report states on February 24, 2020 during a laboratory visit, laboratory personnel described giving buprenorphine once every 24 hours instead of once every 8-12 hours (per the protocol) to mice following craniotomy surgery. The following corrective actions were implemented:

- Proper use of analgesia was discussed at a laboratory meeting on February 25, 2020. Members not in attendance have been informed that they cannot work with animals until after these details are discussed. In preparation for this meeting all animal protocols were reviewed, focusing particularly on surgery, post-op care and euthanasia portions of these protocols.
- The lab manager and research assistant professor developed a two page summary table of all protocols to provide the research group.
- A plan was put in place for laboratory leadership to check laboratory notebooks weekly to ensure IACUC protocol adherence. With a focus on checking surgical and post op records.
- Laboratory leadership met with the faculty veterinarian to determine the best analgesia protocol to use for these protocols moving forward.

It is noted that this project is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Florida 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



Office of the Vice President for Research

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

March 12, 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 D16-00244 (A3377-01) and PHS Policy IV.F.3., provides this report of non-compliance regarding an incident of failure to provide animals analgesia as outlined in the IACUC protocol.

On February 24, 2020 during a laboratory visit, laboratory personnel described giving buprenorphine once every 24 hours instead of once every 8-12 hours (per the protocol) to mice following craniotomy surgery. In addition, surgical records were reviewed and confirmed that buprenorphine was only being given once every 24 hours.

The laboratory implemented the following corrective actions:

1. Proper use of analgesia were discussed at a laboratory meeting on February 25, 2020. Members that were not in attendance at this meeting have been informed that they cannot work with animals until after these details are discussed. In preparation for this meeting all animal protocols were reviewed, focusing particularly on surgery, post-op care and euthanasia portions of these protocols.
2. The lab manager and research assistant professor, worked together to develop a two page summary table of all protocols to provide the research group.
3. A plan was put in place for laboratory leadership to check laboratory notebooks weekly to ensure IACUC protocol adherence. With focus on checking surgical and post op records.
4. Laboratory leadership has met with the faculty vet to determine the best analgesia protocol to use for our protocols moving forward.

The IACUC full committee voted on March 3, 2020 that this incident was a non-compliance and was reportable through the IO to regulatory agencies. No further actions were required.

The Foundation for The Gator Nation

An Equal Opportunity Institution

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

Ref: NIH R01HL122494
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This study is supported by the following grant:
NIH R01HL122494: Central Mechanisms Underlying the Stress Dampening Effects of Acute
Hypernatremia

The NIH funding components have been notified of the noncompliance.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 15, 2020 8:46 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00749838)

Thank you. We will respond soon.
Axel Wolff

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Monday, April 13, 2020 9:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Brown, Reggie (NIH/NHLBI) [E] <brownreg@mail.nih.gov>; Maric-Bilkan, Christine (NIH/NIDDK) [E] <christine.maric-bilkan@nih.gov>
Subject: Report of noncompliance (00749838)

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 funded by NIH and I have cc'd the applicable Program Officials on this email.

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

-Michael

Michael Mahoney
Director of Research Operations and Services
University of Florida | UF Research | PO Box 115500
Grinter (b) (4) PH: (b) (6) | <http://research.ufl.edu>