



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

May 17, 2021

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 8H]

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 May 4, 2021 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida, following up on an initial report on March 29, 2021. According to the information provided, OLAW understands that a buprenorphine vial was not labeled with concentration and expiration date, surgical records did not accurately reflect the amount of buprenorphine dispensed or the correct dates, some mice failed to receive the full amount of the analgesic regimen, and there was a mismatch between amount of analgesic dispensed and the controlled drug records.

The corrective actions consisted of directing the Principal Investigator and staff to use a diluted solution log to account for diluted controlled drugs prepared, amounts withdrawn, remaining balance, and disposal. Vials of controlled substances are to be given a unique identifier, purchase records and packing slips are to be maintained, and disposal records are to be kept. The PI and staff should also use the survival surgery template to record procedures performed, staff must take the survival surgery record training, and the laboratory was placed on enhanced post approval monitoring. The NIH funding component has been informed about this matter.

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 institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



Office of the Vice President for Research

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

May 4, 2021

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 in mice regarding failure to maintain appropriate animal-related records. A preliminary report was sent on March 29, 2021 by Dr. Daniel R. Brown.

On March 23, 2021 during the AAALAC site visit, concerns arose regarding surgical and DEA records. A summary of the issues found during the site visit:

- Buprenorphine vial not labeled with concentration and expiration date.
- Three dates of dispensed buprenorphine totaling 4.8 ml not accounted for in surgical records.
- Some volumes of buprenorphine dispensed did not match the listed dates for buprenorphine in the surgical records.
- According to the post-operative records some mice do not appear to have received the full 48 hours administration of buprenorphine. The DEA record corroborates this.

On March 29, 2021 IACUC staff and an ACS veterinarian met with the PI. Surgical and DEA records were reviewed. The above concerns were discussed, additional concerns were noted:

- It was not possible to match the surgical records to the buprenorphine dispensed in the DEA records. The following corrective actions were recommended on 3/29/21:
 - The PI and lab staff should use a diluted solution log to document the usage details for every controlled substance that has been withdrawn from its original container and mixed with a diluent. The log should include:
 - Amount withdrawn
 - Remaining balance through final disposal
 - The PI and lab staff should use the IACUC recommended survival surgery template, being sure that all sections are filled out at the time various procedures are performed.

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Report of non-compliance
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- It was not possible to follow the controlled substance usage from start to finish. The following corrective actions were recommended on 3/29/21:
 - Give all bottles of controlled substances a unique identifier as soon as they are received, this identifier should match all paperwork.
 - Purchasing records/Packing slips should be maintained and readily available for inspection.
 - Disposal records should be maintained and readily available for inspection.

On April 15, 2021 IACUC staff met with the PI to review the above corrective actions from the initial meeting. All above corrective actions have been completed.

The IACUC full committee voted on April 20, 2021 that this incident was a non-compliance and was reportable through the IO to regulatory agencies. The IACUC has required the following additional corrective actions:

1. All personnel listed on the IACUC protocol must take the new Survival Surgery Record training on myTraining.
2. Within 2 weeks of receipt of this report a post approval monitoring (PAM) visit must be scheduled with IACUC PAM coordinators.

This study is funded by the following grants:

National Institutes of Health-NINDS-R01NS109816-*Multi-pronged Approach to Recalibrating the Inflammatory Cascade in Ischemic Stroke with BET blockade.*

National Institutes of Health-NOA-R01NS103094-*Neurovascular Protection by Adropin in Ischemic Stroke.*

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

mpm gw

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 17, 2021 7:32 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable noncompliance (2021Mar03) [ref:_00D412ElGo._5001K11k2gO:ref]

Thank you for this report. We will respond soon.

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

From: Research - IACUC <iacuc-crm@research.ufl.edu>
Sent: Friday, May 14, 2021 4:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; (b) (6) Aaron (NIH/NINDS) [E] <kinchena@ninds.nih.gov>; Bosetti, Francesca (NIH/NINDS) [E] <frances@mail.nih.gov>; Mayer, Pamela L (NIH/NINDS) [E] <mayerp@ninds.nih.gov>
Subject: Reportable noncompliance (2021Mar03) [ref:_00D412ElGo._5001K11k2gO:ref]

To All Concerned,

Please see that attached report of noncompliance from the University of Florida (Assurance #D16-00244). A preliminary report was sent to OLAW on March 29, 2021 from Dr. Daniel R. Brown.

The animals involved in this noncompliance are funded by the NIH and the applicable program official and grants management specialist are cc'd on this email.

Please confirm receipt and let me know if you have any additional questions.

Best,

(b) (6)



From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 29, 2021 8:39 AM
To: Brown, Daniel R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Potential IACUC Non-Compliance

Thank you for this preliminary report, Dr. Brown. We will start a new case file.
Axel Wolff

From: Brown, Daniel R <drbrown@ufl.edu>
Sent: Monday, March 29, 2021 8:34 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: Potential IACUC Non-Compliance
Importance: High

To All Concerned,

This is preliminary report of a situation potentially involving "failure to adhere to IACUC-approved protocols" and "failure to maintain appropriate animal-related records" at the University of Florida (Assurance #D16-00244). Briefly, concerns have arisen regarding frequency of post-operative analgesia administration, and also regarding accuracy of DEA controlled substance records for an IACUC-approved (UF protocol #201907934) mouse ischemic stroke study funded by multiple sources including NIH.

On 3/29/2021 I directed IACUC staff to initiate an investigation. A final report to our IACUC is expected within 30 days.

Please contact me with any questions or concerns.

Dan Brown



Daniel R. Brown, PhD
Chairman, UF Institutional Animal Care and Use Committee
Associate Professor of Infectious Diseases & Immunology
College of Veterinary Medicine
University of Florida
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