



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 25, 2021

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

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 an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida following up on an initial March 26, 2021 notification by email.

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 the IACUC-approved protocol and failure to provide adequate food to animals. The final report states mice underwent survival surgery and did not receive post-operative analgesia as described in the protocols. The protocols describe buprenorphine to be administered twice a day for 48h. However, mice were only receiving buprenorphine once a day for 48h.

It is further stated 22 mice were fed a special diet. The laboratory maintained 4-5 pellets of food in each cage and checked the animals daily per the report. Within 5d of the animals receiving the special diet, the veterinary staff reported animals as exhibiting signs of dehydration/decreased body condition score. It is stated two mice were found dead and 4 mice required euthanasia. Also, the caging system of the food hopper changed, which allowed mice to push food pellets out of reach if enough pellets were not present to cover the entire hopper surface.

The IACUC full committee reviewed the matter and determined the incident to be a noncompliance and required the following corrective actions:

- Within 2 weeks of receipt of this report, the principal investigator (PI) must submit a protocol modification to indicate that buprenorphine will be given every 8-12 hours for 48 hours.
- The laboratory has been working closely with IACUC staff to improve post-operative recordkeeping. For the next set of surgeries, the PI must send a copy of the post-operative records to the IACUC at the end of each post-operative period.
- Animals must always have access to food and receive chow ad libitum and the food hopper must be filled completely, any deviations must be outlined in the approved protocol.
- Data collected during the time of noncompliance and because of the unapproved activities cannot be used and must be discarded.

It is noted that this work 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,

Jacquelyn  
T. Tubbs -S

Digitally signed by  
Jacquelyn T. Tubbs -S  
Date: 2021.05.25  
15:41:20 -04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
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

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 regarding failure to follow approved protocol, failure to provide analgesia as outlined in protocol, and failure to provide adequate food for mice. A preliminary report was sent on March 26, 2021 by Dr. Daniel R. Brown.

It was self-reported that mice undergoing survival surgery were not given post-op analgesia as described in the IACUC protocols. The protocols indicate that buprenorphine will be given twice a day for at least 48 hours, animals were only receiving buprenorphine once a day for 48 hours.

Additionally, 22 mice were fed a special diet containing high sodium chloride and a lysyl-oxidase inhibitor. The lab was maintaining 4-5 pellets of food in each cage and checking them daily. Within ~5 days of starting the animals on the special diet, vet staff indicated that animals were exhibiting signs of dehydration/decreased body condition score. Two mice were found dead and 4 mice needed to be euthanized for this reason. The caging system/design of the food hopper had been changed by Animal Care Services, allowing mice to push food pellets out of reach if there is not a sufficient number of pellets to cover the entire hopper surface.

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 corrective actions:

1. Within 2 weeks of receipt of this report, the PI must submit a protocol modification to indicate that buprenorphine will be given every 8-12 hours for 48 hours.
2. The laboratory has been working closely with IACUC staff to improve post-operative record keeping. For the next set of surgeries the PI must send a copy of the post-operative records to the IACUC at the end of each post-operative period.

*The Foundation for The Gator Nation*

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Report of non-compliance

May 4, 2021

Page 2

3. Animals must have access to food at all times and be receiving chow ad lib and the food hopper filled completely, any deviation to this must be outlined in the approved protocol.
4. Data collected during the time of noncompliance and as a result of the unapproved activities cannot be used and must be discarded.

The animals involved in this noncompliance were funded by the following grants:

National Institutes of Health-NINDS-R01NS110710-*Inflammatory Mediators and Mechanisms of Cerebral Aneurysm Formation and Rupture*.

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]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 17, 2021 7:28 AM  
**To:** Research - IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable Non-Compliance (2021Mar01) [ ref:\_00D412ElGo.\_5001K11k28C: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 4:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** drbrown@ufl.edu; (b) (6) Kinchen, Aaron (NIH/NINDS) [E] <kinchena@ninds.nih.gov>; Koenig, Jim (NIH/NINDS) [E] <jim.koenig@nih.gov>  
**Subject:** Reportable Non-Compliance (2021Mar01) [ ref:\_00D412ElGo.\_5001K11k28C:ref ]

To All Concerned,

Please see the attached report of a noncompliance from the University of Florida (Assurance #D16-00244). A preliminary report was sent to OLAW on March 26, 2021 via email from Dr. Daniel R. Brown.

The protocol involved in this noncompliance is 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 questions.

Best,

(b) (6)



**Wolff, Axel (NIH/OD) [E]**

43377-86

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 26, 2021 10:20 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 open a new case file.

Axel Wolff

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**From:** Brown, Daniel R <drbrown@ufl.edu>  
**Sent:** Friday, March 26, 2021 10:01 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 situations potentially involving "failure to adhere to IACUC-approved protocols" at the University of Florida (Assurance #D16-00244). Briefly, through routine oversight of one lab's projects it was discovered that post-operative analgesia was being administered to mice with less frequency than required, and also that some mice were malnourished as a result of inadequate monitoring of the food supply by study staff. The IACUC-approved protocols involved (UF #201803748 and #201904771) are cerebral aneurysm studies funded by NIH and private foundation funds.

On 3/26/2021 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  
Gainesville FL 32611-0880 USA  
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