



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

January 28, 2022

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

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 November 8, 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 report on October 15, 2021. According to the information provided, OLAW understands that several deficiencies were identified in a survival surgery in mice. Specifically, provision of analgesia was not documented, one analgesic was given by a different route from what had been approved, a required second dose of analgesic had not been given, surgical records were incomplete, surgery was not conducted aseptically, and warm sterile saline was not provided.

The corrective actions consisted of the Principal Investigator (PI) revoking the animal use privileges of the surgeon responsible. All staff listed on the surgical protocol must undertake retraining, including online and/or hands on, in surgical recordkeeping, managing controlled substances, aseptic technique, rodent anesthesia, and suturing. The PI was also directed to develop a surgical standard operating procedure, surgical checklists, and a post-operative plan which must be approved by the Institutional Animal Care and Use Committee (IACUC). The laboratory was placed under enhanced post-approval monitoring.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the IACUC 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
352-392-9605 Fax

November 8, 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 and PHS Policy IV.F.3., provides this report of a noncompliance regarding multiple survival surgery concerns in mice. This is a follow up to a preliminary report sent to OLAW on October 15, 2021 by IACUC Chair Dr. Daniel R. Brown.

On October 12, 2021 during a post approval monitoring (PAM) visit, PAM coordinator observed a survival surgery procedure, several concerns were noted.

1. The use of Ketamine was not recorded following EHS and IACUC guidelines/Policy.
2. Oral Meloxicam (1.5mg/kg) was given subcutaneously, only injectable Meloxicam (5mg/kg) is approved in the protocol.
3. Surgical records did not include all pertinent information as outlined in the Rodent Survival Surgery Record Policy.
4. Multiple aseptic technique concerns and deviations from the Survival Surgical Policy were noted.
5. Warmed sterile saline was not provided per the protocol.

On October 13, 2021 IACUC staff found that a required second dose of Meloxicam was not given per the IACUC protocol to the animals that underwent surgery on October 12, 2021.

The IACUC full committee voted on November 2, 2021 that this incident was a noncompliance and was reportable through the IO to regulatory agencies. The following corrective actions have been implemented:

1. The PI has elected to remove the surgeon observed during the PAM from all animal handling.

2. All personnel listed as performing surgery on the protocol must complete the following trainings:
 - a. ACS869 Survival Surgery Records (online)
 - b. EHS900 Managing Controlled Substances in Research Laboratories (online)
 - c. ACS840 Aseptic Techniques (online).
 - d. ACS884 Rodent Aseptic Technique Wet Lab (in-person).
 - e. ACS885 Rodent Anesthesia and Monitoring Wet Lab (in person)
 - f. ACS883 Incision and Suture Wet Lab (in person)
3. Within 2 weeks, the PI must submit a surgical SOP to the IACUC, this should include a pre-surgical checklist which can be reviewed the day before any surgery, a surgical checklist which can be used immediately pre-/intra-operatively, and a post-operative plan. This plan must be approved by the IACUC at a future full committee meeting before any surgeries resume.
4. A post approval monitoring (PAM) visit by IACUC staff must occur during the next set of surgeries.

The study is funded by the following grant:

National Institutes of Health-NIAID-R01AI145559-*Unraveling Cryptococcus neoformans mechanisms of brain invasion and colonization*

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

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 15, 2021 7:07 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable noncompliance (2021Oct01) [ref:_00D412ElGo._5001K14eO0b:ref]

Thank you for this report. We will send a response soon.

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

From: Research - IACUC <iacuc-crm@research.ufl.edu>
Sent: Friday, November 12, 2021 4:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; mmahoney@ufl.edu; Love, Dona (NIH/NIAID) [E] <dona.love@nih.gov>; Brennan, Yoon-Sun (NIH/NIAID) [E] <yoon-sun.brennan@nih.gov>; (b) (6)
Subject: Reportable noncompliance (2021Oct01) [ref:_00D412ElGo._5001K14eO0b:ref]

To All Concerned,

I am sending the attached report of a noncompliance from the University of Florida (D16-00244). A preliminary report was sent by the IACUC Chair Dr. Daniel R. Brown via email on October 15, 2021.

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 acknowledge receipt and let me know if you have any questions.

(b) (6)



Wolff, Axel (NIH/OD) [E]

A 3327-85

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 18, 2021 7:21 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

From: Brown, Daniel R <drbrown@ufl.edu>
Sent: Friday, October 15, 2021 5:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: Potential IACUC Non-Compliance
Importance: High

o All Concerned,

This is preliminary report of a situation involving analgesic, surgical and post-operative concerns that arose during a post approval monitoring visit on an IACUC-approved protocol at the University of Florida (Assurance #D16-00244). The mouse study involved (UF protocol #202011067) is funded by the NIH.

On 10/14/2021 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.



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

(b) (6)

drbrown@ufl.edu