



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

October 18, 2021

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

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 October 12, 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 September 16 and an update on September 24, 2021. According to the information provided, OLAW understands that three rats undergoing surgery failed to receive the required pre-operative analgesics. The surgeon did not have access to the drug storage cabinet.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) suspending the protocol, suspending the animal use privileges for the surgeon, and directing the rats to be euthanized. The IACUC directed the Principal Investigator to submit a corrective action plan to ensure animal welfare, to submit a surgical standard operating procedure which includes a comprehensive checklist, and to ensure that staff has access to all needed medications. The suspension of the laboratory member remains in effect and the laboratory was placed under enhanced post-approval monitoring. The NIH funding component was notified of the protocol suspension.

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 IACUC to comply with the PHS Policy. Please inform OLAW should future problems arise after the protocol is reinstated or the suspension status changes such as if it is lifted or becomes permanent. Thank you for keeping OLAW apprised on this matter.

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

(b) (4) Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500
(b) (6)

October 12, 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 rats that did not receive analgesia before surgery per the IACUC protocol. This is a follow up to preliminary reports sent to OLAW on September 16 and September 24, 2021 by IACUC Chair Dr. Daniel R. Brown.

3 rats underwent a controlled brain impact survival surgery on 9/14/21. The protocol states that animals will receive Buprenorphine SR pre-operatively for a total coverage of 48 hours. During an IACUC inspection on 9/15/21 it was found that Buprenorphine SR was not given to these 3 animals. Per IACUC/Animal Care Services veterinary recommendations the animals were euthanized on 9/15/21.

During the investigation it was found that, although the study staff member who performed the surgeries knew that pre-operative Buprenorphine SR was required, the animals did not receive any buprenorphine because the surgeon did not have access to the drug storage cabinet before surgeries that day.

On September 21, 2021, due to immediate concerns over animal welfare and overall protocol adherence the IACUC voted to suspend the protocol. In addition, the study staff member who performed the surgery has been suspended by the IACUC from all animal handling work on all animal protocols at UF.

The IACUC full committee voted on October 5, 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 IACUC protocol will remain suspended until the PI completes the following corrective actions:
 - a. Within 2 weeks of receipt of this report, the PI must submit a plan to the

IACUC describing in comprehensive detail how animal welfare compliance will be maintained for all research conducted within the laboratory. This plan must be approved by the IACUC at a future full committee meeting before the suspension may be lifted.

- b. Within 2 weeks of receipt of this report, the PI must submit a surgical SOP to the IACUC. It is strongly recommended that the SOP include 1) a comprehensive pre-surgical checklist which will be reviewed by the PI and surgeon the day before any surgery, 2) a surgical checklist which will be used by the surgeon immediately pre- /intra-operatively, and 3) a post-operative procedural review by senior lab staff immediately following any surgery. This SOP must be approved by the IACUC at a future full committee meeting before the suspension may be lifted.
2. The suspension of the study staff member who performed the surgery in this non-compliance will remain indefinite.
3. All personnel performing procedures in which animals are to receive analgesia must have access to the necessary drugs at all times.
4. A post approval monitoring (PAM) visit by IACUC staff must occur during any surgeries on any IACUC protocol approved for the PI in this non-compliance. Contact the IACUC office to schedule this. Following the initial PAM, follow up PAM visits must be performed for 12 months. The follow up PAM visits may be done by an IACUC staff member and/or ACS veterinary staff and may be announced or unannounced.

This study is funded by the following grant:

- National Institutes of Health: UH3NS106938 NIBA-TBI: Neuro-Imaging and biofluid-based Biomarker Assessments as translational pathophysiological outcome measures in TBI

The NIH funding components have been notified of the adverse event.

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

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 15, 2021 8:37 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Noncompliance (2021Sept01) [ref:_00D412EIGo_5001K13jufs: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: Thursday, October 14, 2021 2:58 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; mmahoney@ufl.edu; Bellgowan, Patrick (NIH/NINDS) [E] <patrick.frostbellgowan@nih.gov>; Blaisdell, Russell (NIH/NINDS) [E] <russell.blaisdell@nih.gov>; (b) (6)
Subject: Reportable Noncompliance (2021Sept01) [ref:_00D412EIGo_5001K13jufs:ref]

To All Concerned

Please see the attached report of a noncompliance from the University of Florida (D16-00244). This is a follow up to preliminary reports sent via email by Dr. Daniel R. Brown on September 16 and September 24, 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)



Walker, Keri (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 24, 2021 9:43 AM
To: Brown, Daniel R; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Update Re: Potential IACUC Non-Compliance

Thank you for this update. We will await the final report.

Keri

*Keri Walker
 Program Analyst
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 6700B Rockledge Dr., Suite 2500
 Bethesda, MD 20892
 301-435-2390
keri.walker@nih.gov*

From: Brown, Daniel R <drbrown@ufl.edu>
Sent: Friday, September 24, 2021 9:22 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Update Re: Potential IACUC Non-Compliance
Importance: High

To All Concerned,

This is an update to the preliminary report sent to OLAW on September 16, 2021 regarding a situation involving failure to adhere to an IACUC-approved protocol at the University of Florida (Assurance #D16-00244).

At its regularly convened meeting on September 21, 2021 the UF IACUC discussed the preliminary report. Due to immediate concerns over animal welfare based on failure to provide appropriate analgesics to animals undergoing survival surgery, and overall protocol adherence, the IACUC voted to suspend protocol 202110145 effective immediately. In addition, one study staff member involved in this incident has been suspended from all animal handling work on all UF IACUC protocols effective immediately. The IACUC will continue its investigation over the next two weeks and will reconvene on October 5, 2021 for a final determination and corrective action plan.

Please contact me with any questions or concerns.

Dan Brown

Wolff, Axel (NIH/OD) [E]

A 3377

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 17, 2021 8:03 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: Thursday, September 16, 2021 8:40 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 involving failure to adhere to an IACUC-approved protocol at the University of Florida (Assurance #D16-00244). Briefly, during an IACUC inspection it was found that 3 rats had undergone survival surgery without the required analgesics. The brain injury study involved (UF protocol #202010145) is funded by NIH.

On 9/16/2021 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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drbrown@ufl.edu