



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 8I]

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 April 1, 2021. According to the information provided, OLAW understands that mouse cages were overcrowded, cage cards were reused, special care sheets were either not filled out or were filled out in advance, mice were not being weaned, sex of mice was not properly identified, some cages did not have food, liquid diet was not given as required, mice were euthanized but this was not described in the protocol, and some euthanized pups had been euthanized without using the secondary physical method. All but one of these incidents involved the same laboratory member. Despite ongoing counseling and retraining, the problems persisted.

The corrective action consisted of revoking the animal use privileges for the responsible individual and appointing another laboratory member. The protocol was amended to reflect these changes as well as a modified breeding scheme and euthanasia. The Institutional Animal Care and Use Committee (IACUC) directed the Principal Investigator to complete the animal work before the protocol expired and the IACUC withdrew the triennial renewal application. Data collected during the conduct of unapproved procedures cannot be used. The NIH funding components were notified about this matter.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

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 a noncompliance in mice regarding failure to follow lab to care as outlined in protocol, failure to wean cages appropriately, failure to ensure laboratory personnel are properly trained in procedures, and failure to follow euthanasia policy. A preliminary report was sent on April 1, 2021 by IACUC Chair Daniel R. Brown.

Animal Care Services (ACS) husbandry and veterinary staff along with IACUC post-approval monitoring (PAM) staff worked with the laboratory over the past 6 months to re-educate lab staff on multiple concerns outlined below. All incidents involved the same laboratory member with the exception of the April 8, 2021 incident.

- 10/08/2020: ACS notified the IACUC office of overcrowding, reuse of cage cards, and Special Care by PI ("purple sheet") forms filled out in advance or not at all. ACS had re-educated lab staff on these concerns.
- 10/29/2020: IACUC PAM discussed Special Care by PI sheets, adding euthanasia to protocol, history of overcrowding and cages not being weaned, and history of reused cage cards. Requested lab staff take ACS Breeding Workshop, AALAS Learning Library Working with the Laboratory Mouse, and schedule training with ACS on how to properly wean and sex mice.
- 11/2/2020: ACS emailed the lab and IACUC staff with concerns of reuse of cage cards, several overcrowd issues, and mis-sexed mice.
- 12/1/2020: ACS reached out to the lab and IACUC staff regarding Special Care by PI cages found without food on 11/24/2020 and 4 instances of reusing cage cards and cages weaned incorrectly. The IACUC manager sent an email to the PI and lab staff regarding the continued concerns and directed them to schedule a training session.
- 12/3/2020: ACS found a cage with ethanol feeder and no purple card.

The Foundation for The Gator Nation

An Equal Opportunity Institution

Report of a noncompliance
May 4, 2021
Page 2

- 12/4/2020: IACUC PAM met with PI and lab staff for training, discussed setting up weaning cages, creating new cage cards, how to handle mice too small to wean, and the use/care of Special Care by PI sheets and cages.
- 12/17/2020: IACUC manager sent a follow-up email directing lab staff to attend Rodent Handling after they failed to attend a scheduled class. Lab staff rescheduled the training and attended on 12/18/2020.
- 2/8/2021: ACS found special care by PI sheets not signed for Sunday 2/7/2021.
- 2/23/2021: ACS found a cage without liquid diet in feeder (purple sheet was signed).
- 3/9/2021: ACS found 2 cages without liquid diet in feeder (purple sheet was signed).
- 4/5/2021: ACS found one cage of mice in CB-118 without food and no special care by PI card. The cage had apparently been changed by the lab on 4/4/2021 but no food was provided at that time.
- 4/8/2021: ACS found a carcass bag in the carcass freezer with 16, P0-P2 pups. All the pups were dead and frozen, it appeared that a secondary method of euthanasia was not used. In addition, Section 19 of the protocol does not have any information on euthanizing animals. This protocol deviation was found on a previous PAM and not corrected by the laboratory.

The IACUC full committee voted on April 20, 2021 that this series of incidents constitutes noncompliance and has required the following corrective actions:

1. Effective immediately, remove the individual involved in the above incidents from all hands-on animal work, and appoint a new member of the laboratory to take on these duties. A modification must be submitted to remove him from the protocol as an animal handler. The PI must provide the IACUC with a plan for this within 1 week of receipt of this report.
2. Within 1 week or receipt of this report, the PI must submit a plan to complete all animal work by the 2018 version of the protocol's expiration date of 5/16/2021. The 2021 triennial renewal application will be withdrawn by the IACUC.
3. Within 1 week or receipt of this report, the PI must modify the 2018 IACUC protocol to remove harem (up to 4 females) breeding schemes. The lab will only do monogamous mating going forward. This should minimize the overcrowding concerns.
4. Within 1 week or receipt of this report, the PI must modify the 2018 IACUC protocol to add euthanasia.
5. Data collected during the time of the noncompliance and as a result of the unapproved activities cannot be used and must be discarded.

The animals involved in this noncompliance are funded by the following grant:

National Institutes of Health-NIAAA-5R01AA028035-*Regulation of the pro-fibrotic connective tissue growth.*

The NIH funding components have been notified of the noncompliance.

Report of a noncompliance
May 4, 2021
Page 3

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 JW

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 17, 2021 7:33 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable noncompliance (2021Mar04) [ref:_00D412ElGo._5001K11k2Bn: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, May 14, 2021 4:46 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; (b) (6) Herlihy, Celia (NIH/NIAAA) [E] <celia.herlihy@nih.gov>; Radaeva, Svetlana (NIH/NIAAA) [E] <sradaeva@mail.nih.gov>
Subject: Reportable noncompliance (2021Mar04) [ref:_00D412ElGo._5001K11k2Bn:ref]

To All Concerned,

Please see the attached report of noncompliance from the University of Florida (Assurance #D16-00244). A preliminary report was sent on April 1, 2021 by Dr. Daniel R. Brown.

The animals involved in this noncompliance were 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)



A3377-

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 2, 2021 7:37 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: Thursday, April 1, 2021 9:59 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6)
Subject: Potential IACUC Non-Compliance

To All Concerned,

This is preliminary report of a situation potentially involving "failure to adhere to IACUC-approved protocols; chronic failure to provide space for animals; failure to correct deficiencies identified in a timely manner; and, failure to maintain appropriate animal-related records" at the University of Florida (Assurance #D16-00244). Briefly, vivarium husbandry staff and IACUC post-approval monitoring have identified several concerns regarding conduct of an IACUC-approved (UF protocol #201808859) mouse ischemic stroke study funded by NIH.

On 3/31/2021 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
Tel [REDACTED] (b) (6)
Fax [REDACTED]
drbrown@ufl.edu

From: Daniel Brown <drbrown@ufl.edu>
Date: Monday, March 29, 2021 at 8:32 AM
To: "OLAW Division of Compliance Oversight (NIH/OD)" <olawdco@od.nih.gov>

Cc: [REDACTED]

(b) (6)

Subject: Potential IACUC Non-Compliance

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

Gainesville FL 32611-0880 USA

Tel [REDACTED] (b) (6)

Fax [REDACTED]

drbrown@ufl.edu