



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

June 11, 2021

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

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 June 1, 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 the following deficiencies were identified during facility inspections: uncapped syringes of cocaine in an unlocked room, expired medications, non-pharmaceutical controlled drugs not approved on the protocol, and non-impervious surface items stored in animal procedure spaces.

The corrective actions consisted of amending the protocol to account for the non-pharmaceutical grade drugs, counseling the Principal Investigator (PI) and staff on proper handling of filled syringes, fixing physical room deficiencies, stopping use and storage of the non-impervious surface items, having the PI develop standard operating procedures covering handling of drugs, and placing the laboratory 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 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



A3377

Office of the Vice President for Research

223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500
352-392-1582
352-392-9605 Fax

June 1, 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 regarding aseptic technique for handling of diluted agents, controlled substance security, expired substances, non-pharmaceutical grade drugs being used when pharmaceutical grade is available (not outlined in protocol), and deviations from the policy on impervious surfaces. A preliminary report was sent on April 1, 2021 by IACUC Chair Daniel R. Brown.

During the AAALAC site visit on March 23, 2021 the following concerns were noted:

1. Multiple uncapped syringes containing cocaine for self-administration in rodents were stored in an unlocked room.

During the Spring 2021 Semiannual inspections on March 19, 2021 the following concerns were noted:

1. Expired carprofen and expired cefazolin were found. According to the IACUC Policy on Expired Drugs, Supplies, and Materials for Use On or In Animals for Research, Teaching or Testing, expired drugs, fluids, medical supplies and devices cannot be used on or in live animals.
2. There were a number of non-pharmaceutical grade drugs in the lock box (oxycodone, cocaine, pentobarbital). The protocol does not outline these as being non-pharmaceutical grade. According to the Policy for Approved Substance/Drug Use in Protocols it is the University of Florida IACUC policy that substances administered to animals under an IACUC protocol must be FDA-approved pharmaceutical grade products. If a non-pharmaceutical grade formulation is requested and there is a FDA-approved pharmaceutical grade formulation available, a written scientific justification for this request must be described in the original protocol or subsequent modifications.
3. Multiple impervious surfaces (foam, cardboard, etc.) being stored in animal procedure spaces were found. According to the IACUC Policy on Impervious Surfaces unsealed wood and/or cardboard, Styrofoam, cloth/fabric or any other non-impervious surface are not acceptable especially if in direct contact with the animals or their urine or feces.

The IACUC full committee voted on May 4, 2021 that these incidents were a noncompliance and the following corrective actions are required:

1. A modification has been submitted to the current IACUC protocols to outline the non-pharmaceutical grade drugs being used.
2. ACS veterinary and IACUC staff met with the PI and lab staff to discuss proper storage of filled syringes. All syringes containing a controlled substance must be secured and all filled syringes must be properly capped when not in use in order to maintain sterility and prevent evaporation.
3. A work order has been placed to fix the paint on the ceiling and to remove the dishwasher found during the semiannual inspection.
4. The foam insulation being stored was used to elevate the plus maze per IACUC recommendation. The IACUC is no longer recommending this be used, the PI has removed the foam insulation.
5. Within 2 weeks of receipt of this report, the PI must develop and submit to the IACUC an SOP regarding preparation, storage, and general processes related to the drug administration.
6. Within 2 weeks of receipt of this report, the PI must schedule a post approval monitoring visit with IACUC staff.

The animals involved in this incident are funded by the following grants:

- National Institutes of Health: R33DA045140: *Identifying patterns of human polysubstance use to guide development of rodent models*
- National Institutes of Health: R03DA050118: *A novel model of oxycodone seeking that considers sex and stress susceptibility*

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: Wednesday, June 9, 2021 7:34 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Noncompliance (2021Apr01) [ref:_00D412EIGo_5001K11IduP:ref]

Thank you. 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: Tuesday, June 8, 2021 12:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) drbrown@ufl.edu; Bucheimer, Amy (NIH/NIDA) [E] <bucheimera@mail.nih.gov>; Moore, Holly (NIH/NIDA) [E] <holly.moore@nih.gov>; Greenwood, Lennin (NIH/NIDA) [E] <lennin.greenwood@nih.gov>
Subject: Reportable Noncompliance (2021Apr01) [ref:_00D412EIGo_5001K11IduP:ref]

To All Concerned,

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

Best,

(b) (6)



Wolff, Axel (NIH/OD) [E]

A3377-8J

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 2, 2021 7:38 AM
To: Brown, Daniel R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Potential IACUC Non-Compliance

Thank you. We will open a new case file.
Axel Wolff

From: Brown, Daniel R <drbrown@ufl.edu>
Sent: Thursday, April 1, 2021 10:24 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; 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, routine monitoring identified several concerns regarding conduct of IACUC-approved (UF protocols #201907973 and 201908010) rat drug addiction studies funded by NIH.

On 04/01/2021 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
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Gainesville FL 32611-0880 USA
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