



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 13, 2020

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 6W]

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 April 30, 2020 letter reporting an incident of non-compliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Florida. Your letter supplements information in an April 1, 2020 prompt preliminary email report. According to the information provided, OLAW understands that on March 23, 2020 you directed all investigators that, due to the COVID-19 pandemic, no new animal experiments were to be initiated. On March 27, 2020 a veterinarian reported that, despite being instructed to not do so, a PI and post-doc initiated a special diet experiment in rats. Inconsistencies were also found in the animal records for the rats. The animals involved in this incident were on a study funded by the PHS.

Corrective and preventive actions included the lab stopping all experiments on March 27, 2020 and euthanizing the rats. The lab must create an SOP discussing "PI to care" procedures and all lab staff members must be trained on the SOP. The PI and all lab members must meet with IACUC staff to discuss all of the lab's SOPs, laboratory records and protocols. The lab staff was also encouraged to take immediate action to correct current and past special care by PI concerns and to implement culture change within the laboratory.

OLAW believes that the actions taken by the University of Florida are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. It is understood that the funding component has been notified of the noncompliance and that no unauthorized charges were made against the grant. OLAW appreciates being informed of this issue and finds no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)



Office of the Vice President for Research

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

April 30, 2020

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 noncompliance regarding an incident of failure to follow Institution Official (IO) and veterinary directive and failure to maintain appropriate animal records. This incident was first reported to Dr. Brent Morse, OLAW, on April 1, 2020 via email by Dr. Daniel R. Brown, IACUC Chair.

On March 23, 2020 the IO directed all investigators that, as part of the institution's response to the COVID-19 pandemic, no new animal experiments were to be initiated. On March 27, 2020 it was reported to the IACUC by an Animal Care Services (ACS) veterinarian that the PI and a post-doc, despite being told directly by the veterinarian not to do so, had initiated new rat studies involving special diets. In addition, there were concerns regarding inconsistencies in the animal records for the rats.

On April 2 and April 3, 2020 an IACUC subcommittee met with the PI and post-doc involved in the incident. The IACUC full committee voted on April 21, 2020 that the PI and study staff failed to follow the *Special Care by Principal Investigator – Rodents* ACS Guideline and the IO's directive that no new animal experiments were to be initiated, and that this was a non-compliance reportable through the IO to regulatory agencies (OLAW, AWA, AAALAC).

The following corrective actions were implemented as a result of the non-compliance.

1. On March 27, 2020 the laboratory stopped all active rat experiments and euthanized all rats.
2. The laboratory must create an SOP discussing all "PI to care" procedures and all members of the laboratory must be formally trained on the SOP.

3. The PI and all laboratory members must meet with a member of the IACUC staff to review all approved IACUC protocols, laboratory records and SOP's.

In addition to the corrective actions stated above the IACUC strongly encouraged the laboratory to take immediate action to correct current and past special care by PI concerns and to implement culture change within the laboratory.

This study is supported by the following grant:

- NIH- R01-DK-116004: *Evaluating the therapeutic potential of vagal CART circuitry for treating metabolic disease*

The NIH funding components have been notified of the noncompliance and we certify that no unallowable costs were charged during the noncompliant period.

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: Friday, May 1, 2020 7:12 AM
To: Mahoney,Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00834099)

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

From: Mahoney,Michael P <mmahoney@ufl.edu>
Sent: Thursday, April 30, 2020 9:00 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Whipp, Lesley (NIH/NIDDK) [E] <whipp2@niddk.nih.gov>; Hyde, James (NIH/NIDDK) [E] <hydej@extra.niddk.nih.gov>
Subject: Report of noncompliance (00834099)

Dr. Morse,

I am sending the attached report of noncompliance from the University of Florida. The IACUC chair sent a preliminary report for this event on April 1st, 2020 (email below). The protocol involved in this noncompliance is funded by NIH and I have cc'd the applicable Program Officials on this email.

Please acknowledge receipt and let me know if you have any issues.

-Michael

Michael Mahoney
Director of Research Operations and Services
University of Florida | UF Research | PO Box 115500
Grinter (b) (4) PH: (b) (6) | <http://research.ufl.edu>

From: Brown,Daniel R
Sent: Wednesday, April 1, 2020 10:20 AM
To: olawdco@od.nih.gov
Cc: (b) (6) Mahoney,Michael P
Subject: Potential IACUC Non-Compliance (UF #2020Apr01)

To All Concerned,

This is preliminary report of a situation potentially involving failure of animal care and use personnel to carry out veterinary orders, and failure to maintain appropriate animal-related records at the University of Florida (Assurance #A3377-01). Briefly, in March 2020 in response to the COVID-19 pandemic our Institutional Official directed all investigators that no new animal experiments were to be initiated. A facility veterinarian subsequently reported that certain lab staff, despite being told directly by the veterinarian not to do so, did initiate new rodent studies involving special diets, and also back-dated cage cards on multiple cages in an attempt to disguise this. Animal welfare was not compromised. The IACUC-approved obesity protocol involved (UF #201910305) is funded by NIH.

I will appoint a subcommittee of two regular IACUC members to conduct an investigation (UF #2020Apr01). Their report to our IACUC will be expected within approximately 30 days. Please contact me with any questions or concerns.

Dan Brown

Daniel R. Brown, Ph.D.
Chairman, UF Institutional Animal Care and Use Committee
Associate Professor of Infectious Diseases and Immunology
College of Veterinary Medicine
Campus Mail Box 110880
University of Florida
Veterinary Academic Building (b) (4)
2015 SW 16th Avenue
Gainesville FL 32608 USA
Tel (b) (6)
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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 2, 2020 9:15 AM
To: Brown, Daniel R
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Potential IACUC Non-Compliance (UF #2020Apr01)

Thank you for this report, Dr. Brown. I'll start a new case file and look forward to receiving the final report from the IO when possible.

Axel Wolff

From: Brown, Daniel R <drbrown@ufl.edu>
Sent: Wednesday, April 1, 2020 10:21 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Mahoney, Michael P <mmahoney@ufl.edu>
Subject: Potential IACUC Non-Compliance (UF #2020Apr01)
Importance: High

To All Concerned,

This is preliminary report of a situation potentially involving failure of animal care and use personnel to carry out veterinary orders, and failure to maintain appropriate animal-related records at the University of Florida (Assurance #A3377-01). Briefly, in March 2020 in response to the COVID-19 pandemic our Institutional Official directed all investigators that no new animal experiments were to be initiated. A facility veterinarian subsequently reported that certain lab staff, despite being told directly by the veterinarian not to do so, did initiate new rodent studies involving special diets, and also back-dated cage cards on multiple cages in an attempt to disguise this. Animal welfare was not compromised. The IACUC-approved obesity protocol involved (UF #201910305) is funded by NIH.

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Dan Brown

Daniel R. Brown, Ph.D.

Chairman, UF Institutional Animal Care and Use Committee
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