



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

April 22, 2020

Re: Animal Welfare Assurance  
A3377-01 [OLAW Case 7C]

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 February 26, 2020 letter reporting several non-compliances with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Florida. According to the information provided, OLAW understands that on June 4 and June 14, 2019 a lab performed an unauthorized cannula replacement surgery in a mouse and cannula replacement in a rat. On October 1, 2019 veterinary technicians recommended the lab euthanize a mouse. The lab indicated they would euthanize the mouse but it was found dead the next day. The animals are part of a study that is PHS funded.

Although the lab had been working with Animal Care Services (ACS) to improve communication, several corrective and preventive actions were discussed during the investigation. These included a change in the method of record keeping by the lab and including the lab manager on all emails from ACS to allow follow-up by the lab manager. The PI also submitted a protocol amendment to reduce cannula damage or clogging.

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 informed of the non-compliance issues. 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



Office of the Vice President for Research

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

February 26, 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 multiple incidences of failure to follow veterinary directive.

On June 4, 2019 and June 14, 2019 the laboratory performed an unapproved catheter (rat) and cannula (mouse) replacement surgery without consulting with the veterinary staff. In August 2019, the veterinary staff educated the laboratory that a veterinarian consultation must take place prior to performing repairs if not approved on the IACUC protocol.

On October, 1, 2019 the veterinary technicians recommended that the laboratory have a mouse evaluated by a staff veterinarian or euthanized due to poor overall condition. The laboratory indicated that they would euthanize the mouse, however the laboratory failed to euthanize the animal and it was found dead by Animal Care Services staff the following day.

During the investigation by an IACUC subcommittee, the PI indicated that the lab had been trying to work with ACS staff to improve communication within the lab related to animal care issues. The laboratory has modified several methods of communication and record keeping to prevent this from happening again. The PI has modified the protocol to help minimize the risk of damage or clogging to the catheter after discussions with and recommendations by the vets.

The following corrective actions were discussed during the investigation:

1. The laboratory must ensure that record keeping be done in a way that ACS staff can readily assess the procedures performed on an animal to facilitate aiding an animal that may not be doing well. This could be done on cage cards (space permitting) or else by a log that could be readily referred to.

*The Foundation for The Gator Nation*

An Equal Opportunity Institution

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

Retrieved from Animal Research Laboratory Overview (ARLO)

2. To ensure good communication regarding sick animals, a new procedure has been implemented whereby the lab manager, as well as other lab personnel, receives all emails from ACS. The lab manager will then ensure that a member of the lab has been identified to deal with the issues, and will also do a follow up check to ensure that all issues are dealt with by the end of the day.

The IACUC full committee voted on January 21, 2020 that this incident was a non-compliance and was reportable through the IO to regulatory agencies. In addition to the above corrective actions the IACUC has requested that within 2 weeks that the PI update the committee on the progress of the corrective actions stated above.

This study is supported by the following grant:

- NIH R01DK116004: Evaluating the therapeutic potential of vagal CART circuitry for treating metabolic disease
- NIH R21DK110511: Microbiome-vagal-brain signaling: impact on the reward system and food intake

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

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 15, 2020 8:44 AM  
**To:** Mahoney, Michael P  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of noncompliance (00708732)

Thank you. We will respond soon.  
Axel Wolff

**From:** Mahoney, Michael P <mmahoney@ufl.edu>  
**Sent:** Monday, April 13, 2020 9:50 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>; Smits, Jeni (NIH/NIDDK) [E] <jeni.smits@nih.gov>; Maruvada, Padma (NIH/NIDDK) [E] <maruvadp@mail.nih.gov>  
**Subject:** Report of noncompliance (00708732)

Dr. Morse,

I am sending the attached report of noncompliance from the University of Florida. UF did not send a preliminary report for this event. 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

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Michael Mahoney  
Director of Research Operations and Services  
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