



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) 480-3377

June 8, 2020

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

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 28, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Florida Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states on May 1, 2020 Animal Care Services found 4 cages of nude mice with bilateral subcutaneous flank tumors that had exceeded approved tumor size limits. Following review of the protocol, it was discovered that nude mice were not approved for use on the protocol, bilateral tumors were also not approved on the protocol and mice were 10-16d past experimental endpoints. As a result, the principal investigator (PI) developed a plan describing how compliance with the protocol would be upheld and reinforced within the lab. Also, all laboratory members listed on the approved IACUC protocol will complete or repeat online training course entitled Working with the IACUC and Common Compliance Issues in the AALAS library. The IACUC reviewed the incident on May 19, 2020 and determined it to be reportable.

It is noted that this research is not supported by PHS funds. This Office assumes the IACUC found the PI's corrective action plan acceptable. Based on its assessment of this explanation, OLAW understands that the University of Florida has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2020.06.08 11:52:22 -04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3377-7H



Office of the Vice President for Research

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

May 28, 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 A3377-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding deviations from approved protocol and tumors past experimental endpoint.

On May 1, 2020, Animal Care Services (ACS) found four cages of nude mice with bilateral subcutaneous flank tumors over approved size limits. After reviewing the approved protocol, several additional issues were found. Mice were 10-16 days past the approved experimental end point, the nude mouse strain (NU/J) was not approved on the protocol, and bilateral tumors were not approved on the protocol (unilateral tumors were approved).

To prevent this kind of incident in the future the Principal Investigator has created a plan outlining how compliance with the animal protocol will be maintained and reinforced within the laboratory and all laboratory members listed on the approved IACUC protocol must take/retake Working with the IACUC and Common Compliance Issues in the AALAS library.

On May 19, 2020 the IACUC reviewed the incident and determined that it was reportable non-compliance.

This study is not PHS funded.

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

The Foundation for The Gator Nation

An Equal Opportunity Institution

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Retrieved from Animal Research Laboratory Overview (ARLO)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 3, 2020 7:13 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00893281)

Thank you for this preliminary report, Dr. Mahoney. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Tuesday, June 2, 2020 1:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of noncompliance (00893281)

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 not funded by PHS.

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

-Michael

Michael Mahoney

Director of Research Operations and Services
University of Florida
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