



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

July 27, 2020

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

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 July 13, 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. According to the information provided, OLAW understands that on June 8, 2020 an approved procedure was performed on a rabbit. The rabbit received analgesia (Meloxicam) prior to the procedure. On post procedure day 3 it was determined that the animal did not receive Meloxicam 24 hours after the first dose per the protocol. The animals involved in this study are not on a study funded by the PHS.

Corrective and preventive actions included the laboratory developing a treatment documentation sheet which lists the treatment regimens outlined in the protocol. The laboratory will initial and date the treatments as they administer them. The PI and laboratory personnel will meet to review the protocol prior to initiating any new procedures.

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. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. 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
Dr. Robert M. Gibbens, USDA, APHIS, AC



Office of the Vice President for Research

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

July 13, 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 non-compliance regarding rabbits and failure to provide analgesia per the approved IACUC protocol.

On June 8, 2020 an approved procedure was performed on the right eye of a rabbit. The rabbit received analgesia (Meloxicam) prior to the procedure. The following day during post procedure checks, the laboratory noted that the animal was recovering well and behaving normally. On post procedure day 3 the animal was reported to the veterinary staff for ocular inflammation where it was discovered that the animal did not receive Meloxicam 24 hours after the first dose per the protocol.

The approved protocol addresses the formation of a sub conjunctival drainage bleb, having some involvement of the eyelid and potentially being confused as inflammation/swelling. This bleb is not thought to be painful and is expected to resolve to a smaller size within a day or two with or without anti-inflammatory treatment.

The IACUC full committee voted on July 7, 2020 that this incident was a non-compliance and was reportable. The following corrective actions were requested by the Committee:

- The laboratory is to develop a treatment documentation sheet which lists the treatment regimens outlined in the protocol, the laboratory will initial and date the treatments as they administer them.
- The PI and laboratory personnel will meet to review the protocol prior to initiating any new procedures.

Non-Compliance
July 13, 2020
Page 2

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

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 24, 2020 7:19 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00960703)

Thank you for this report, Dr. Mahoney. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Wednesday, July 22, 2020 5:42 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of noncompliance (00960703)

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
Grinter Hall (b) (4)
PO Box 115500
Gainesville, FL 32611-5500
(b) (6)
research.ufl.edu

