



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

January 24, 2022

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

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 January 13, 2022 letter reporting an adverse event involving a research horse at the University of Florida. According to the information provided, OLAW understands that following an Institutional Animal Care and Use Committee- approved intestinal surgery, a horse experienced complications following anesthetic recovery. The animal repeatedly attempted to stand and when it did, the right hind fetlock became disarticulated and penetrated the skin.

The immediate action taken in response consisted of euthanizing the horse. No abnormalities were noted during the surgery or in the application of the anesthesia.

Based on its assessment of this explanation, OLAW concurs that the incident was an unexpected adverse event. As the study was not PHS-funded and there was no noncompliance identified, it was not necessary to report the matter to OLAW. While not exactly meeting the definition found in the examples of what not to report in NOT-OD-05-034, this unexpected negative outcome occurring during the provision of standard veterinary care could be matched to the following statement: "Examples of situations *not* normally required to be reported: animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed." We recommend conferring with OLAW as to whether an incident qualifies for reporting or not. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC



A3377-SW

UF Research
Office of the Vice President for Research

223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-0000
352-392-9271

January 13, 2022

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 and PHS Policy IV.F.3., provides this report of an adverse event regarding accidental injury leading to euthanasia of a horse. A preliminary report was not sent to OLAW regarding this adverse event.

On December 7, 2021 a research horse underwent IACUC-approved intestinal surgery. The surgery went as planned with no intraoperative complications, but recovery from anesthesia was complicated by strong but uncoordinated attempts to stand. In the final attempt the horse stood with extreme difficulty and the right hind fetlock became disarticulated and penetrated the skin. The horse was immediately euthanized according to the approved protocol. The Attending Veterinarian was notified immediately. The anesthesia record was reviewed and there were no concerns regarding the documentation of care according to protocol and standard veterinary procedures for abdominal surgery in the horse.

The IACUC full committee voted on December 21, 2021 that this incident was an adverse event and was reportable through the IO to regulatory agencies.

This study is not funded by PHS.

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, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

David Norton, PhD
Vice President for Research
Institutional Official

MPM

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 19, 2022 7:28 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Adverse Event Report (2021Dec01) [ref:_00D412ElGo._5001K15aYLQ:ref]

Thank you for this report. 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, January 18, 2022 10:52 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) drbrown@ufl.edu
Subject: [EXTERNAL] Adverse Event Report (2021Dec01) [ref:_00D412ElGo._5001K15aYLQ:ref]

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

To All Concerned,

I am sending the attached report of an adverse event from the University of Florida (D16-00244).

The protocol involved is not funded by the PHS.

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

Best,

(b) (6)

