



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 12, 2021

Re: Animal Welfare Assurance
A3391-01 [OLAW Case 3J]

Dr. Christopher O'Byrne
Vice President and Associate Dean
Research Administration & Operations
Wake Forest University
Medical Center Boulevard
Winston-Salem, NC 27157

Dear Dr. O'Byrne,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 29, 2021 letter in response to OLAW's June 11, 2021 request for information regarding an instance of noncompliance PHS Policy on Humane Care and Use of Laboratory Animals at Wake Forest University. According to the information provided, OLAW understands that all 10 animals presented as hunched, lethargic and dehydrated and four of the surviving animals responded to treatment with fluid therapy for five days, heat support for three days along with moistened chow. Veterinary checks of the animals were performed as needed.

OLAW appreciates the prompt consideration of this matter by Wake Forest University which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concern. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L.
Lukovsky-
akhsanov -S

Digitally signed by Nicole
L. Lukovsky-akhsanov -S
Date: 2021.07.12 08:28:21
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

June 29, 2021

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Dear Dr. Lukovsky-Akhsanov,

This letter is in response to your correspondence dated June 11, 2021, Re: Animal Welfare Assurance A3391-01 (OLAW Case 3J). In that letter you request further information on the following:

- Please provide information regarding direct animal welfare concerns related to the noncompliance including any required medical interventions and animal disposition for the remaining four animals.

We appreciate the opportunity to provide clarification on this point. The requested information is outlined below.

- All of the 10 mice presented as hunched, lethargic and had a skin tent (dehydrated).
- The four that survived responded to treatment that consisted of fluid therapy for five days, along with wet chow.
- For the first three days, they were also provided with heat support.
- Veterinary checks were performed twice daily for the first three days, then once daily thereafter for fluid support.

The surviving mice experienced a full recovery.

Wake Forest is committed to protecting the welfare of animals used in research. Please contact me if you need any additional information.

Sincerely,

(b) (6)


Christopher O'Byrne
Vice President & Associate Dean
Research Administration & Operations
Institutional Official

Cc: Dr. Czoty, Chairperson, Wake Forest University IACUC
AAALAC International

Walker, Keri (NIH/OD) [E]

From: [REDACTED] (b) (6)
Sent: Wednesday, June 30, 2021 3:37 PM
To: Walker, Keri (NIH/OD) [E]
Cc: [REDACTED] (b) (6); Paul Czoty; Christopher OByrne; AAALAC International (accredit@AAALAC.org)
Subject: Wake Forest Response to OLAW Case A3391-3J
Attachments: WF Response to OLAW Case 3J.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms. Walker and Dr. Lukovsky-Akhsanov,

Attached please find the Wake Forest response for additional information regarding OLAW Case A3391-3J.

Please contact us with any questions or concerns.

Thank you,

[REDACTED] (b) (6)



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June 11, 2021

Re: Animal Welfare Assurance
A3391-01 [OLAW Case 3J]

Dr. Christopher O'Byrne
Vice President and Associate Dean
Research Administration & Operations
Wake Forest University
Medical Center Boulevard
Winston-Salem, NC 27157

Dear Dr. O'Byrne,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 2, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wake Forest University. According to the information provided, OLAW understands that ketoprofen, which was not approved on the protocol, was administered to 10 mice as a post-operative analgesic. In addition, the dose administered was incorrect leading to the death of six animals. The study was PHS funded.

As a corrective measure, the Principal Investigator retrained staff on the importance of reviewing the protocol prior to starting procedures and using approved drugs, the research team was retrained on calculating drug doses and program oversight staff will continue to monitor animal care and use procedures to ensure compliance with IACUC approved processes.

OLAW appreciates the prompt consideration of this matter by Wake Forest University which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests the following information:

- Please provide information regarding direct animal welfare concerns related to the noncompliance including any required medical interventions and animal disposition for the remaining four animals.

We look forward to your responses to the to the additional information request by **July 2, 2021**. Please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-
akhsanov-S

Digitally signed by Nicole L.
Lukovsky-akhsanov-S
Date: 2021.06.11 11:52:02
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

May 2, 2021

Axel V. Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance A3391-01
Wake Forest incident number AWC21-005

Dear Dr. Wolff:

This is an official notification that the Wake Forest University (WFU) Animal Care & Use Program identified and resolved a deviation from standard procedure, which the WFU Institutional Animal Care and Use Committee (IACUC) determined must be reported to your office.

PHS funding:

The following PHS funds provided support this project: R37-AA17531; R01 AA26551, R21 AA26455; P50 AA26117

In accordance with federal expectations, the WF IACUC has forwarded information regarding this incident to our the WF School of Medicine sponsored research office, which will review relevant direct costs associated with the procurement, care and use of the animal(s) related to this deviation. Relevant costs will be paid from a nonfederal source, as appropriate.

Incident:

Ketoprofen, which was not listed in the approved protocol, was administered to 10 mice as a post-operative analgesic. In addition the dose was incorrect resulting in the death of 6 animals.

Preliminary Report:

No preliminary report was made to OLAW regarding this incident.

Resolution:

The IACUC approved the following actions to resolve this incident:

1. The PI retrained his staff on the importance of reviewing the protocol prior to starting procedures and only using drugs listed in the protocol.
2. The research team member was retrained on calculating drug doses.
3. All actions have been completed/implemented at this time, and the WFU IACUC considers this matter closed. Program oversight staff will continue to monitor animal care and use procedures to ensure compliance with IACUC approved processes.

WFU is committed to protecting the welfare of animals used in research and teaching. Please, contact (b) (6) if you have questions or comments regarding any aspect of this incident or its resolution.

Sincerely yours,

(b) (6)

Christopher O'Byrne
Vice President & Associate Dean
Research Administration & Operations
Institutional Official

cc: Dr. Czoty, Chairperson, WF IACUC
AAALAC International

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 7, 2021 7:23 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report on AWC21-004 and AWC21-005

Thank you for these reports. We will send responses soon.

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

From: (b) (6)
Sent: Wednesday, May 5, 2021 11:50 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Paul Czoty
<pczoty@wakehealth.edu>; AAALAC International (accredit@AAALAC.org) <accredit@AAALAC.org>
Subject: Final Report on AWC21-004 and AWC21-005

Please find the final report on the management of the noncompliance incidents AWC21-004 and AWC21-005 that involved the care and use of animals in research or teaching at Wake Forest University (Assurance No. D16-00248 (A3391-01)).

Please contact us with any questions or concerns.

Thank you,
(b) (6)

(b) (6)