



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 28, 2021

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

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 July 22, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wake Forest University (Wake Forest incident number AWC21-009). We received the initial report via a telephone communication on July 8, 2021. According to the information provided, OLAW understands that in a protocol investigating neurobiology in a domestic cat model, two complications arose in separate animals in June 2021: 1) uncontrolled post-procedural pain, and 2) post-procedural infection that resulted in an animal death. These animals were supported by PHS funding. Relevant costs will be paid from a nonfederal source, as appropriate.

A review of this investigator's research records found inadequate documentation in procedural and other research records, which included the failure to provide post-operative analgesia as directed in the protocol. The inadequate documentation included inconsistencies between reported stock solution use and reported dosing in animal care records, failure to document drug administration, the use of drug regimens approved on a different protocol for a similar procedure, and apparent typos that if correct, would have a negative impact on animal care.

In the case of post-procedural pain noted above, the analgesic regimen provided by the researcher was insufficient to relieve pain between doses and required veterinary intervention. The animal fully recovered with good pain control thereafter. The required post-procedural administration of an NSAID drug (analgesic) was not consistently provided, because the researcher wrongly believed it was to be administered only when signs of pain were evident. This constitutes a failure to follow the approved protocol. On one occasion, this lack of adequate analgesia prompted veterinary intervention to relieve pain. Similar deficiencies in record keeping and protocol adherence were found in 15 separate records managed by this researcher. The infection and death were deemed unexpected complications.

Corrective and preventive actions:

1. The IACUC Chair directed the immediate removal of the researcher from the approved IACUC protocol. The IACUC acknowledged this decision without dissent at the next convened meeting.
2. The researcher was removed from all approved protocols, and for unrelated reasons the researcher is leaving the institution on July 31, 2021, and

3. The approved protocols under this principal investigator will undergo monthly, then quarterly, post-approval monitoring for adherence to approved IACUC protocols and good procedural record keeping for the next year to ensure full compliance, and
4. Any serious or continuing noncompliance will result in further disciplinary action.

The prompt consideration of this matter by Wake Forest University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. Please include the animal species in all future final reports. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

**Brent C. Morse -S**

Digitally signed by Brent C.

Morse -S

Date: 2021.07.29 07:29:35 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: Assistant Director, Animal Care and Use Committee  
IACUC contact  
Dr. Robert M. Gibbens, USDA, APHIS, AC

July 22, 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 AWC21-009

Dear Dr. Wolff,

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

PHS funding:

The following PHS funds provided support to this project: R01 EY 026919

In accordance with federal expectations, the IACUC forwards information regarding this incident to the appropriate sponsored research office for the review of direct costs associated with the procurement, care, and use of the animal(s) related to this deviation, as needed. Relevant costs will be paid from a nonfederal source, as appropriate.

Incident:

In a protocol investigating neurobiology in an animal model, two complications arose in separate animals in June 2021: 1) uncontrolled post-procedural pain, and 2) post-procedural infection that resulted in an animal death.

The close timing of these events prompted an immediate review of this investigator's research records. The review found inadequate documentation in procedural and other research records, which included the failure to provide post-operative analgesia as directed in the protocol. The inadequate documentation included inconsistencies between reported stock solution use and reported dosing in animal care records, failure to document drug administration, the use of drug regimens approved on a different protocol for a similar procedure, and apparent typos that if correct, would have a negative impact on animal care.

In the case of post-procedural pain noted above (1), the correct dose and timing of analgesia was documented in the medical record, demonstrating the researcher's intent to be compliant with the approved IACUC protocol, but the analgesic regimen was insufficient to relieve pain between doses and required veterinary intervention. The animal fully recovered with good pain control thereafter. However, the review also found that, for a different procedure under the same approved protocol, the required post-procedural administration of an NSAID drug (analgesic) was not consistently provided,

because the researcher wrongly believed it was to be administered only when signs of pain were evident. This constitutes a failure to follow the approved protocol. On one occasion, this lack of adequate analgesia prompted veterinary intervention to relieve pain. Similar deficiencies in record keeping and protocol adherence were found in 15 separate records managed by this researcher. The infection and death (2) were deemed unexpected complications.

Immediate Actions:

On the same day as the initial review, the IACUC Chair directed the immediate removal of the researcher from the approved IACUC protocol. The IACUC acknowledged this decision without dissent at the next convened meeting.

Preliminary Report:

A preliminary report was provided on this issue to your office on July 8, 2021 by phone message to Dr. Morse.

Resolution:

The principal investigator was responsive and engaged in establishing corrective actions, and a subsequent review of research records within the laboratory and independently by IACUC representatives found good record keeping practices by all other laboratory members.

The IACUC determined that these errors were a serious deviation from acceptable record keeping and expected adherence to approved protocols.

The IACUC approved the following actions to resolve this incident:

1. The researcher was removed from all approved protocols, and for unrelated reasons the researcher is leaving the institution on July 31, 2021, and
2. The approved protocols under this principal investigator will undergo monthly then quarterly post-approval monitoring for adherence to approved IACUC protocols and good procedural record keeping for the next year to ensure full compliance, and
3. Any serious or continuing noncompliance will result in further disciplinary action.

Wake Forest is committed to protecting the welfare of animals used in research and teaching. Please contact me if you have questions or comments regarding any aspect of this incident or its resolution.

Sincerely,

(b) (6)

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

cc: Dr. James Jordan, Chairperson, Wake Forest University IACUC  
AAALAC International

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, July 28, 2021 8:00 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report on AWC21-009

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

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

**From:** (b) (6)  
**Sent:** Tuesday, July 27, 2021 10:07 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) AAALAC International (accredit@AAALAC.org)  
<accredit@AAALAC.org>  
**Subject:** Final Report on AWC21-009

Please find the final report on the management of the noncompliance incident AWC21-009 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)



## Initial Report of Noncompliance

By: BCM

Date: 7/8/2021

Time: Voicemail

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Wake Forest Univ.

Assurance number: A3391

Did incident involve PHS funded activity? Yes

Funding component: NEI

Was funding component contacted (if necessary): ?

What happened? Wake Forest Reference # AWC21-009

During records review it was determined that the researchers had failed to adhere to the approved protocol.

Species involved: Felis

Personnel involved: researchers

Dates and times: ?

Animal deaths: no

Projected plan and schedule for correction/prevention (if known):

Under review. All current procedures now per approved protocol.

Projected submission to OLAW of final report from Institutional Official:

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Case #