



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

March 1, 2022

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

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 February 18, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Wake Forest University (WFU). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the WFU Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal activities without prior IACUC review and approval. The final report states a research team self-reported an incident involving animals that underwent a hypercapnia challenge procedure that was not in the approved IACUC protocol. It is understood the procedure is approved in a different protocol by the same Principal Investigator (PI). It is stated the research team is well trained on this procedure and no adverse events or negative impact on animal health were observed.

In response to the incident, a Notification of Correction Letter was provided to the PI emphasizing the importance of strictly adhering to the IACUC-approved protocol. Per the report, all actions have been completed and the IACUC considers this matter resolved.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Wake Forest University 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: 2022.03.01  
15:57:54 -05'00'

Jacquelyn Tubbs, DVM, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

February 18, 2022

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 AWC22-001

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: U01AI150578

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:

A protocol deviation was self-reported by a research team in which animals underwent a hypercapnia challenge procedure that was not in the approved IACUC protocol. This procedure is approved in a different protocol by the same principal investigator. The research team is well trained on this procedure and no adverse events or negative impact on animal health occurred.

Preliminary Report:

No preliminary report was made to OLAW regarding this incident.

Resolution:

The IACUC approved the following actions to resolve this incident:

A Notification of Correction Letter was sent to the PI reiterating the importance of strictly adhering to the approved IACUC protocol. The IACUC acknowledges the self-report by the PI.

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. 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, February 23, 2022 8:28 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report on AWC22-001

Thank you for this report, (b) (6) We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Monday, February 21, 2022 2:57 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Jim Jordan/SurgSci  
Cardiothoracic Surgery <jeordan@wakehealth.edu>; AAALAC International (accredit@AAALAC.org)  
<accredit@AAALAC.org>  
**Subject:** [EXTERNAL] Final Report on AWC22-001

**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.

Please find the final report on the management of the noncompliance incident AWC22-001 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)