



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

June 11, 2021

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

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 March 9, 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 retro-orbital blood collection was performed on 38 mice however the method of blood sampling was not approved on the IACUC protocol. This study was PHS funded.

As a corrective measure, a Notification of Correction Letter was provided to the Principal Investigator (PI) reminding of the importance to verify the procedure as described in the approved protocol, the PI was informed that no data obtained from unapproved collections can be published or presented, an amendment was submitted and approved for retro-orbital blood collection and relevant costs due to the deviation will be paid from a non-federal source. 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. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. 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: 2021.06.11 11:52:30 -04'00'

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

cc: IACUC contact

March 9, 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 AWC21-002

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: R01 HL132035

In accordance with federal expectations, the WF IACUC has forwarded information regarding this incident to 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:

Retro-orbital blood collection was performed on 38 mice. Blood collection was approved in the IACUC protocol; however, the method of retro orbital collection was not. The lab staff member that bled the mice is very experienced, having done > 200 retro-orbital bleeds.

Preliminary Report:

No preliminary report was made to OLAW regarding this incident.

Resolution:

The IACUC approved the following actions to resolve this incident:

1. A Notification of Correction Letter was sent to the PI reiterating the importance of reminding lab staff to verify the procedure to be performed is described in the appropriate approved protocol.
2. An amendment was submitted and has been approved by the IACUC to include the retro-orbital blood collection procedure.
3. The PI was informed that no data obtained from the unapproved blood collections can be published, presented, or used in a proposal for funding.
4. 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)

(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

Walker, Keri (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 19, 2021 8:20 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report on AWC21-002

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

Keri

*Keri Walker
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390
keri.walker@nih.gov*

From: (b) (6)
Sent: Friday, April 16, 2021 11:15 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Paul Czoty
<pczoty@wakehealth.edu> (b) (6) AAALAC International
<accredit@AAALAC.org> <accredit@AAALAC.org>
Subject: Final report on AWC21-002

Please find the final report on the management of the noncompliance incident AWC21-002 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)