



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) 402-7065

March 12, 2019

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

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 19, 2019 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 twelve mice died after being given an experimental compound that included an incorrect ingredient which was not described in the approved protocol. A laboratory member had incorrectly constituted the mixture using a wrong component.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) counseling the Principal Investigator (PI) on relevant policies and compliance and sending a Notification of Correction. The PI responded that the individual who prepared the compound will no longer prepare animal drugs and that laboratory staff must demonstrate proficiency in preparing experimental compounds for use in animals. Program oversight staff will monitor the laboratory to ensure compliance.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

February 19, 2019

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 208927982

Re: Animal Welfare Assurance D16-00248 (A3391-01)
AWC19-002; USDA customer number 825; AAALAC #00008

Dear Dr. Wolff:

The Wake Forest University Animal Care & Use Program experienced a deviation from standard procedure that was determined by the Wake Forest University (WFU) Institutional Animal Care and Use Committee (IACUC) to be reportable to the NIH Office of Laboratory Animal Welfare.

PHS Funding: 5R21AR072806-02

If appropriate, we will forward to our sponsored research office and all direct costs associated with the procurement, care and use of the animal(s) involved in this non-compliance event will be removed from this account and Invoiced to and paid from a nonfederal source.

Incident:

Twelve mice died after being injected with an experimental drug. It was determined that the drug compound administered was incorrectly made by a member of the lab staff. Dimethyl Sulfoxide (DMSO) was used as a vehicle instead of saline which resulted in the deaths of the animals.

Preliminary Report:

No preliminary report was made to OLAW.

Resolution:

The WFU IACUC contacted the Principal Investigator and discussed current institutional policies and regulatory compliance related to this concern. The IACUC approved the following actions to resolve this incident:

1. A Notification of Correction Letter was sent to the PI. Per the PI, the lab staff member will no longer be making drugs to be used in animals. All lab members must demonstrate to the PI that they know how to correctly make Injectable drugs.

All actions have been completed/implemented at this time and the WFU IACUC considers this non-compliance matter closed. The program oversight staff will continue to monitor animal care and use procedures to assure compliance with IACUC approved processes.

Wake Forest University is committed to protecting the welfare of animals used in research. Please contact Dr. David Lyons of our IACUC (dlyons@wakehealth.edu or (b) (6)) if you desire additional information regarding any aspect of this incident or the subsequent resolution.

Sincerely yours,

(b) (6)

Christopher O'Byrne
Vice President and Associate Dean
Research Administration and Operations
Institutional Official
Wake Forest School of Medicine

cc: Dr. Czoty, Chairperson, WF IACUC
AAALAC International (all OLAW NCI letter)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, March 7, 2019 2:11 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report on AWC19-002

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: Thursday, March 7, 2019 1:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: David J. Lyons <dlyons@wakehealth.edu>; (b) (6) Paul Czoty
<pczoty@wakehealth.edu>; Christopher OByrne <cobyrne@wakehealth.edu>; (b) (6)
(b) (6) AAALAC International (accredit@AAALAC.org) <accredit@AAALAC.org>
Subject: Final Report on AWC19-002

Please find the final report on the management of the noncompliance incident AWC19-002 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)

A large rectangular area of the document is redacted with a solid grey box. The redaction covers the body of the email, likely containing the final report mentioned in the subject line.