



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

September 11, 2018

Re: Animal Welfare Assurance
A3391-01 [OLAW Case 2Z]

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 August 21, 2018 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 three nonhuman primates underwent a cystocentesis procedure which was not listed on the approved protocol. No adverse effects were noted in the monkeys.

The corrective actions consisted of counseling the Principal Investigator (PI), issuing a Notification of Correction Letter to the PI, and having the PI ensure that staff reviews the content of the protocols before conducting animal activities.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution 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
Robert Gibbens, D.V.M., USDA-APHIS-AC

August 21, 2018

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
AWC18-011; 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: P40 OD010965. 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 noncompliance event will be removed from this account and invoiced to and paid from a nonfederal source.

Incident: Three monkeys underwent a cytocentesis procedure that was not on the approved protocol. The procedure is on other protocols of the same investigator. The procedure was performed correctly and without incident. There were no animal welfare concerns.

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 Principal Investigator.
2. The Principal Investigator implemented a corrective action plan to review protocols and verify procedures to ensure this would not happen again.

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.

WFU is committed to protecting the welfare of animals used in research. Please contact (b) (6) of our IACUC (Em: (b) (6)) if you wish additional information regarding any aspect of this incident or the subsequent 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 (all OLAW NCI letter)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, September 10, 2018 12:50 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Reports on AWC18-010 and AWC18-011

Thank you for these reports, (b) (6) We will send responses soon.

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

From: (b) (6)@wakehealth.edu]
Sent: Monday, September 10, 2018 12:47 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Paul Czoty <pczoty@wakehealth.edu>; Christopher OByrne <cobyrne@wakehealth.edu>; (b) (6)
(b) (6)
Subject: Final Reports on AWC18-010 and AWC18-011

Please find the final reports on the management of the noncompliance incidents numbered above 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)