



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 12, 2018

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

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 April 3, 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 a hemostat had been left on the umbilical vessels following a C-section of a ewe and was retained following closure. The ewe's condition deteriorated and she required euthanasia. Upon necropsy the hemostat was discovered as well as ruptured uterine horns which had led to toxemia.

The preventive actions consisted of notifying and counseling the Principal Investigator and surgeon, and adding instrument counts to the surgical record sheet.

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

April 3, 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 D16-00248 (A3391-01)
AWC18-004; 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:

1R01HL135853-01A1. 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

Five days following a c-section to deliver twin lambs, the ewe's condition deteriorated and, despite supportive treatment, was humanely euthanized due to poor prognosis. The necropsy revealed rupture of both uterine horns and the placenta protrusion into the abdominal cavity which likely resulted in sepsis/toxemia and the decline in health. The surgical incision site was found to be pristine, with sutures intact. As an incidental finding, a hemostat was found clamped to the umbilical vessels of the left placenta, which is the reason for this report.

Preliminary Report

No Preliminary Report was sent 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 Action Letter was sent to the PI and to the surgeon who performed the c-section.
2. An instrument count has been added to the surgical record sheet.

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) @wakehealth.edu; Ph: (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. Vachharajani, Chairperson, WF IACUC
AAALAC International (all OLAW NCI letter)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 12, 2018 10:57 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Vidula T. Vachharajani; Christopher OByrne (b) (6) (b) (6)
Subject: RE: Final Reports on AWC18-004 and AWC18-006

Thank you for these two final reports. We will send official responses soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)@wakehealth.edu]
Sent: Thursday, April 12, 2018 9:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Vidula T. Vachharajani <Vidula.Vachharajani@wakehealth.edu>; Christopher OByrne <cobyne@wakehealth.edu>; (b) (6)@wakehealth.edu>; (b) (6)@wakehealth.edu>; (b) (6)@wakehealth.edu>
Subject: Final Reports on AWC18-004 and AWC18-006

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)