



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

January 9, 2019

Re: Animal Welfare Assurance
A3469-01 [OLAW Case Q]

Dr. Michael R. Van Scott
Senior Associate Vice Chancellor for Research
East Carolina University
2200 South Charles Blvd., MS 157
Greenville, North Carolina 27834

Dear Dr. Van Scott,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 8, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at East Carolina University. According to the information provided, OLAW understands that on a rat study there were post-procedural complications, inconsistent record keeping, and failure to follow the approved protocol. The Principal Investigator had started the study prior to finishing the pilot study and seven rats were subjected to repeat procedures although this was not included in the protocol.

The corrective actions consisted of the veterinary staff assisting the investigators to improve surgical and procedural techniques. The research staff was retrained in use of aseptic technique and one problematic procedure was eliminated. The PI and staff were retrained, no animal activities can be conducted until training has been completed, and the laboratory was placed under enhanced Institutional Animal Care and Use Committee (IACUC) oversight.

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



A3469-Q

Office of the Vice Chancellor
Division of Research, Economic Development & Engagement
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8 January 2019

Axel Wolff, MS, DVM, Director
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360 MSC 7982
6705 Rockledge Drive
Bethesda, Maryland 20892-7982

Dear Dr. Wolff:

At the August 26, 2018, IACUC meeting, concerns related to a protocol using rats as a model were reported, including postprocedural complications, discrepancies in record keeping, and noncompliance with the approved protocol.

When first alerted to the problems, as an immediate response, the veterinary staff had worked extensively with the research staff and improved surgical and procedural techniques. Following re-instruction by the veterinary staff in aseptic technique, the postprocedural complication rate improved. Additionally, the researcher removed one problematic procedure from the study.

At the August 26 meeting, a subcommittee was appointed to review all records associated with the project.

The subcommittee conducted a thorough investigation and review of all records and reported their findings to the IACUC at a convened meeting on December 10, 2018. The IACUC voted to report the incident to OLAW.

The subcommittee findings included:

1. The PI initiated work on the main study prior to completion of the pilot study.
2. The PI performed repeat procedures on seven animals which was not consistent with his approved protocol.
3. There were inconsistencies in the PI's documentation of procedures.

The IACUC discussed these findings and determined the following additional corrective actions would be applied:

1. The PI must submit procedure records to the IACUC on a monthly basis until further notice.
2. The PI and all lab personnel must complete CITI Training as assigned by the committee.
3. No projects can begin prior to completion of the above training.

The affected study was partially supported by NIH R01 A10-0241.

Please let us know if you have any additional questions.

Sincerely,
(b) (6)

Michael R. Van Scott, PhD
Senior Associate Vice Chancellor for Research
Institutional Official

www.ecu.edu

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, January 9, 2019 7:18 AM
To: (b) (6)
Subject: RE: Study partially supported by NIH R01 A10-0241

Thank you for this report, (b) (6). We will send a response soon. Please send all future reports to olawdco@od.nih.gov
Axel Wolff

From: (b) (6)
Sent: Tuesday, January 8, 2019 6:27 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: O'Rourke, Dorcas <OROURKED@ecu.edu>; (b) (6)
(b) (6) Van Scott, Michael <VANSCOTTMI@ecu.edu>; (b) (6)
(b) (6)
Subject: Study partially supported by NIH R01 A10-0241

Dear Dr. Wolff –

Happy New Year!

Please find attached letter as referenced in the subject line.

Should you require additional information, please feel free to contact Dr. Michael Van Scott at (b) (6) vanscottmi@ecu.edu, or Dr. Dorcas O'Rourke at (b) (6) orourke@ecu.edu.

Respectfully,

(b) (6)