



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

February 4, 2019

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

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 a Principal Investigator (PI) conducting a rat study began work on the main study before the pilot study was completed, performed repeat procedures which were not described in the protocol, and had inconsistent documentation. Rats also experienced post-procedural complications.

The corrective actions consisted of the veterinary staff working with the research staff to help improve surgical technique and reduce post-procedural problems. The Institutional Animal Care and Use Committee (IACUC) required the PI to submit procedure records monthly, to have the PI and staff undertake retraining, and to not start additional projects until the training is complete.

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. In future please send all final noncompliance reports to [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov). The report should still be signed by the Institutional Official and then scanned and submitted to the OLAW mailbox. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Office of the Vice Chancellor  
 Division of Research, Economic Development & Engagement  
 Greenville Centre, Suite 1500 | 2200 South Charles Boulevard | Mail Stop 157  
 East Carolina University | Greenville, NC 27858-4353  
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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 post-procedural 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 post-procedural 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