



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

May 9, 2019

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

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 May 7, 2019 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at East Carolina University, following up on an initial telephone report on February 22, 2019. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Mice were used in a toxicity study that had not been approved by the Institutional Animal Care and Use Committee (IACUC).

Corrective actions: The IACUC required the Principal Investigator (PI) and staff to undertake retraining, to submit a protocol amendment, and to receive retraining on the use of procedure cards and biosafety issues.

- 2) A student in the same laboratory sustained a needle stick while handling a toxic compound. The animal care staff had not been notified about the use of hazardous chemicals as required.

Corrective actions: The IACUC prohibited handling of toxins by unapproved personnel and suspended all protocols involving hazards for this PI. All laboratory staff must certify understanding of the content of all protocols, including use of hazard agents. The animals were placed on a holding protocol and the PI was asked to respond regarding prevention of noncompliance. This did not occur and therefore all five protocols were terminated. The co-investigators submitted their own new protocols, completed required training along with staff, and submitted the certifications. The protocols were approved, the original PI is not conducting animal activities, and none of these activities were PHS supported.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Division of Research, Economic Development, & Engagement
1500 Greenville Centre | 2200 South Charles Boulevard | Mail Stop 157
East Carolina University | Greenville, NC 27858-4353
252-328-9479 office | vanscottmi@ecu.edu

7 May 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:

This letter serves as a final report concerning two noncompliances by a single investigator at East Carolina University, Assurance #A3469-01. An initial verbal telephone report was made by Dr. Dorcas O'Rourke, Attending Veterinarian, on 02/22/19. The IACUC's actions concerning both incidents are as follows.

Incident #1

The Principal Investigator attempted an unapproved toxicity study on mice in November 2018. The incident was reported to the IACUC at the 12/10/18 convened meeting, and an investigation into noncompliance was conducted. A report of the investigating subcommittee's findings was presented to the convened IACUC on 01/14/19, and the IACUC sent a letter to the PI on 01/16/19 with the following requirements for the PI and all laboratory personnel:

1. Completion of retraining, specifically utilizing CITI modules and exams;
2. Submission of amendment detailing all toxicity studies, including rigorous justification, humane endpoints, and proper methodology;
3. Completion of retraining and exam on the proper use of procedure cards; and
4. Face-to-face training with Biosafety officers and EH&S personnel on safe handling and use of chemicals.

All lab personnel completed the CITI training by 01/30/19.

An amendment describing toxicity studies was submitted for IACUC review at the convened meeting on 01/14/19 and brought back for full committee review on 02/4/19. This amendment had not been approved at the time of the second noncompliance incident.

Procedure card training was not completed at the time of the second noncompliance incident.

Face-to-face safety training occurred on 02/8/19.

www.ecu.edu

Incident #2

On 02/4/19, a student working in the PI's laboratory sustained a needle stick while handling a toxic compound. The student had just been added to the protocol to perform a specific behavioral test on the mice. It was also discovered that the PI had not notified animal care staff of hazardous chemical use as required by the approved protocol and institutional policy. The IACUC chair immediately called a convened meeting, and on 02/6/19, the IACUC voted to stop all handling of toxins by unapproved persons and appointed a subcommittee to investigate other allegations of noncompliance regarding this protocol. The subcommittee conducted an exhaustive investigation which included interviewing all lab members. The PI did not meet with the subcommittee on either of the agreed-on dates, 02/8/19 and 02/14/19. The IACUC met on 02/18/19, discussed the findings of the subcommittee, and voted to suspend all protocols involving hazards (4) that were currently approved for the PI until the following criteria were met:

1. All laboratory personnel signed attestations that they had read and understood all protocols that they were approved to participate in, including specific procedures related to use of hazards;
2. The PI demonstrated to the IACUC how he would ensure that these types of noncompliance would not re-occur.

All animals assigned to the suspended protocols were subsequently placed on a holding protocol, and no one from the lab group was permitted access.

The PI was asked to provide a response to the IACUC by the 04/8/19 meeting, either in writing or in person. He did neither. On 04/16/19, the PI terminated all five of his protocols. Other scientists who had been working as co-investigators on these terminated protocols submitted new protocols of their own. They and their lab personnel completed all specific training as prescribed by the IACUC, signed attestations as required, and were approved to continue their work independently. The responsible PI is not currently conducting research using live vertebrate animals.

NIH supported none of the work described in either of the noncompliances.

ECU remains committed to upholding the highest standards of animal care and use, and we feel that the actions taken were appropriate in this situation. Please let us know if you require additional information.

Sincerely,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, May 8, 2019 10:00 AM
To: (b) (6)
Subject: RE: Final report - noncompliances by a single PI

Thank you for this report, (b) (6) I will respond soon. In future please send all final noncompliance reports to olawdco@od.nih.gov

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

From: (b) (6)
Sent: Wednesday, May 8, 2019 9:56 AM
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: Final report - noncompliances by a single PI

Dear Dr. Wolff –

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) orourked@ecu.edu.

Respectfully,

(b) (6)



Initial Report of Noncompliance

By: *aw*

Date: *2/22/19*

Time: *9:45*

Name of Person reporting: *Dorcas O'Rourke*
 Telephone #: *(b) (6)*
 Fax #:
 Email:

Name of Institution: *East Carolina U*
 Assurance number: *A3469*

Did incident involve PHS funded activity? *No*
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened?

- 1) Mice died after receiving an approved dose of drug*
- 2) Not following protocol, used benzocaine agent + didn't tell caretakers*

Species involved: *Mice* *1 person got needle stick*
 Personnel involved:
 Dates and times:
 Animal deaths: *Yes*

Projected plan and schedule for correction/prevention (if known): _____
Put up signs, suspend protocols, mice on holding protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
 Case # _____