



Office of Research Administration & Compliance  
Division of Research, Economic Development, & Engagement  
1516 Greenville Centre | 2200 South Charles Boulevard | Mail Stop 157  
Greenville, NC 27858-4353 | [www.ecu.edu/rede](http://www.ecu.edu/rede)  
252-328-9479 office | [vanscottmi@ecu.edu](mailto:vanscottmi@ecu.edu)

6 June 2018

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:

Please accept this interim report (verbal report filed in November 2017 by Dr. Dorcas O'Rourke, Attending Veterinarian) from East Carolina University (PHS Assurance A3469-01), describing immediate actions taken, subsequent IACUC investigation, and permanent corrections being instituted following a limited power failure resulting in loss of aeration to multiple fish tanks in one laboratory. The loss of aeration resulted in the deaths of 22 newly-collected wild fish. There was no morbidity or mortality resulting from aeration loss to acclimated wild fish in the laboratory.

Following the incident, the Attending Veterinarian (AV) was informed, and all fish from the lab were immediately relocated to an animal facility that had not been impacted by the outage. These fish will remain there permanently. The AV reported the incident to the IACUC, and a subcommittee was appointed to gather information regarding the outage and make recommendations for preventing future occurrences. The subcommittee met independently with the PI and her students, the department chair and manager, and members of Facility Services. They then presented their findings and recommendations to the convened IACUC, and the IACUC approved these recommendations.

The fish are now permanently housed in an animal facility, and signage indicating emergency contact information for laboratory personnel, veterinarians, and facility personnel is prominently posted. The circuit breaker that failed was completely replaced; a second main breaker is being installed, and an automated monitoring and alarm system is being purchased.

A final report will be submitted when installation of the automated monitoring and alarm system is complete. The impacted animals were not part of a PHS funded research project.

Please let us know if you have additional questions.

Sincerely,

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

[www.ecu.edu](http://www.ecu.edu)



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  
252-328-9471 office | [goldenj17@ecu.edu](mailto:goldenj17@ecu.edu)

12 December 2018

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:

Please accept this final report (verbal report filed in November 2017 by Dr. Dorcas O'Rourke, Attending Veterinarian, and interim written report filed June 6, 2018 by me) from East Carolina University (PHS Assurance A3469-01). As a final mitigation, ECU installed an automated system to monitor electrical power for environmental support systems in the animal facilities. In the case of power failure, local alarms sound, and staff are alerted of the power failure, enabling them to either address the malfunction or relocate the animals. The system has been tested and is functioning properly. Please let us know if you require additional information.

Sincerely,

A handwritten signature in blue ink that reads "Michael Van Scott".

Michael Van Scott, Ph.D.  
Institutional Official  
Senior Associate Vice Chancellor for Research

[www.ecu.edu](http://www.ecu.edu)



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

December 13, 2018

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

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 December 12 and June 6, 2018 letters reporting an adverse event involving fish at East Carolina University, following up on an initial telephone report on November 17, 2017. According to the information provided, OLAW understands that 22 captive wild fish died due to loss of tank aeration caused by a limited power failure.

The immediate action taken upon discovery consisted of relocating the surviving fish to another animal facility with power. The fish will be housed in the other facility permanently and emergency contact information has been posted. The failed circuit breaker was replaced, a second one was also installed, and an automated system with alarm was installed which will monitor power for environmental support systems in the animal facilities. The system was tested and is working correctly and will alert staff in the event of a power failure.

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 institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

cc: IACUC Chair

**From:** AAALAC International  
**To:** "vanscottmi@ecu.edu"  
**Cc:** "orourke@ecu.edu"; "davenport@ecu.edu"  
**Subject:** Acknowledgement of Institutional Correspondence: File # 000677  
**Date:** Monday, December 31, 2018 10:26:29 AM

---



AAALAC International acknowledges receipt of your communications providing notification of incidences of noncompliance at your institution, together with an account of the corrective actions taken.

As you are aware, the Institutional Animal Care and Use Committee (IACUC) has a responsibility for ensuring that animal procedures conducted conform with the approved protocol and institutional policies. The Institutional Official, IACUC, veterinary staff and research personnel can effectively work as a team to establish a culture of compliance at the institution that will minimize occurrences of noncompliance. Your communication of this program issue is in accord with AAALAC International's Rules of Accreditation. This information, reflecting an updated status, will be incorporated into your AAALAC International file, which is reviewed periodically by the Council on Accreditation.

Your continuing communication of programmatic changes or concerns as they occur is appreciated. If AAALAC International can be of assistance, please feel free to contact me.

Sincerely,

A handwritten signature in black ink that reads "Gary L. Borkowski".

Gary L. Borkowski, D.V.M., M.S.  
Global Director

GLB:blk

As a reminder...

Report immediately: unexpected animal deaths • natural disasters • significant animal rights activities • inappropriate euthanasia • allegations • complaints • animal welfare concerns • lack of veterinary care changes • unit contact changes

Report on the Annual Report: protocol violations • protocol noncompliance • protocol suspensions • changes in facility size, location, name, IACUC/Ethics Committee/Animal Care Committee composition changes

This message and its attachments may contain information subject to professional confidentiality, and can only be used by the person or entity who is the intended recipient of the email. Its reproduction or distribution without the express permission of AAALAC International is not allowed. If you are not the intended recipient, please delete it and notify the sender. According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we remind you that personal data may be stored in a file owned by AAALAC International for the intended use of communication with our associates, and that you have the option of exercising rights of data access, rectification, cancellation, and opposition at: [accredit@aaalac.org](mailto:accredit@aaalac.org)





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.
- 2.
- 3.

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 [REDACTED]

Please let us know if you have any additional questions.

Sincerely,

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



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

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,

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

cc: IACUC Chair

**From:** [AAALAC International](#)  
**To:** ["vanscottmi@ecu.edu"](mailto:vanscottmi@ecu.edu)  
**Cc:** ["jacuc@ecu.edu"](mailto:jacuc@ecu.edu); ["orourke@ecu.edu"](mailto:orourke@ecu.edu)  
**Subject:** Acknowledgement of Institutional Correspondence: File # 000677  
**Date:** Thursday, January 31, 2019 12:55:43 PM

---



AAALAC International acknowledges receipt of your communications providing notification of noncompliance at your institution, together with an account of the corrective actions taken.

As you are aware, the Institutional Animal Care and Use Committee (IACUC) has a responsibility for ensuring that animal procedures conducted conform with the approved protocol and institutional policies. The Institutional Official, IACUC, veterinary staff and research personnel can effectively work as a team to establish a culture of compliance at the institution that will minimize occurrences of noncompliance. Your communication of this program issue is in accord with AAALAC International's Rules of Accreditation. This information, reflecting an updated status, will be incorporated into your AAALAC International file, which is reviewed periodically by the Council on Accreditation.

Your continuing communication of programmatic changes or concerns as they occur is appreciated. If AAALAC International can be of assistance, please feel free to contact me.

Sincerely,

A handwritten signature in black ink that reads "Gary L. Borkowski". The signature is written in a cursive, flowing style.

Gary L. Borkowski, D.V.M., M.S.  
Global Director

GLB:blk

As a reminder...

Report immediately: unexpected animal deaths • natural disasters • significant animal rights activities • inappropriate euthanasia • allegations • complaints • animal welfare concerns • lack of veterinary care changes • unit contact changes

Report on the Annual Report: protocol violations • protocol noncompliance • protocol suspensions • changes in facility size, location, name, IACUC/Ethics Committee/Animal Care Committee composition changes

This message and its attachments may contain information subject to professional confidentiality, and can only be used by the person or entity who is the intended recipient of the email. Its reproduction or distribution without the express permission of AAALAC International is not allowed. If you are not the intended recipient, please delete it and notify the sender. According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we remind you that personal data may be stored in a file owned by AAALAC International for the intended use of communication with our associates, and that you have the option of exercising rights of data access, rectification, cancellation, and opposition at: [accredit@aaalac.org](mailto:accredit@aaalac.org)



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](mailto: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 [REDACTED] 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](http://www.ecu.edu)



Incident #2

On 02/4/19, [REDACTED]

[REDACTED] It was also discovered that the PI had not [REDACTED]

[REDACTED] 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. [REDACTED]

[REDACTED] The IACUC met on 02/18/19, discussed the findings of the subcommittee, and voted to [REDACTED]

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.

[REDACTED]

[REDACTED] 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. [REDACTED]

[REDACTED] 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,



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



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:

[REDACTED]

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.

[REDACTED]

Corrective actions: The IACUC prohibited handling of toxins by unapproved personnel and [REDACTED]. 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 [REDACTED]. The co-investigators submitted their own new protocols, completed required training along with staff, and submitted the certifications. The protocols were approved, [REDACTED] and none of these activities were [REDACTED] 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,

*Axel Wolff, M.S., D.V.M.*

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

cc: IACUC Chair

**From:** [AAALAC International](#)  
**To:** ["orourke@ecu.edu"](mailto:orourke@ecu.edu)  
**Cc:** ["davenport@ecu.edu"](mailto:davenport@ecu.edu)  
**Subject:** Acknowledgement of Institutional Correspondence: File # 000677  
**Date:** Friday, June 07, 2019 9:11:03 AM

---



AAALAC International acknowledges receipt of communication providing notification of incidences of noncompliance at your institution, together with an account of the corrective actions taken.

As you are aware, the Institutional Animal Care and Use Committee (IACUC) has a responsibility for ensuring that animal procedures conducted conform with the approved protocol and institutional policies. The Institutional Official, IACUC, veterinary staff and research personnel can effectively work as a team to establish a culture of compliance at the institution that will minimize occurrences of noncompliance. Your communication of this program issue is in accord with AAALAC International's Rules of Accreditation. This information, reflecting an updated status, will be incorporated into your AAALAC International file, which is reviewed periodically by the Council on Accreditation.

Your continuing communication of programmatic changes or concerns as they occur is appreciated. If AAALAC International can be of assistance, please feel free to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Gary L. Borkowski".

Gary L. Borkowski, D.V.M., M.S.  
Global Director

GLB:blk

As a reminder...

Report immediately: unexpected animal deaths • natural disasters • significant animal rights activities • inappropriate euthanasia • allegations • complaints • animal welfare concerns • lack of veterinary care changes • unit contact changes

Report on the Annual Report: protocol violations • protocol noncompliance • protocol suspensions • changes in facility size, location, name, IACUC/Ethics Committee/Animal Care Committee composition changes

This message and its attachments may contain information subject to professional confidentiality, and can only be used by the person or entity who is the intended recipient of the email. Its reproduction or distribution without the express permission of AAALAC International is not allowed. If you are not the intended recipient, please delete it and notify the sender. According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we remind you that personal data may be stored in a file owned by AAALAC International for the intended use of communication with our associates, and that you have the option of exercising rights of data access, rectification, cancellation, and opposition at: [accredit@aaalac.org](mailto:accredit@aaalac.org)