



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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 9, 2019

Re: Animal Welfare Assurance
A3854-01 [OLAW Case N]

Dr. Gary K. Ostrander
Vice President for Research
Florida State University
3012 Westcott North – PO Box 3061330
Tallahassee, FL 32306-1330

Dear Dr. Ostrander,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 21, 2019 letter reporting an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Florida State University (FSU). According to the information provided, OLAW understands that on July 10, 2019, an adverse event report was filed detailing animal deaths associated with a temporal lobe epilepsy project, which involved rats as the research model. The FSU Animal Care and Use Committee (ACUC) was informed the animal deaths appeared to be associated with the administration of a drug via an unapproved route. A subcommittee was appointed to investigate the concern and concluded there had been protocol drift resulting in noncompliance. Noncompliance was determined to be related to: 1) administration of the drug 2) lack of documentation of post-procedural care 3) failure to obtain an exemption for individual animal housing. At a convened meeting on September 25, 2019, the investigative committee recommended several actions, which were accepted by unanimous vote of the quorum. The recommended actions are as follows:

- Animal activity involving seizure induction is suspended until the current protocol has been amended and approved to accurately reflect all procedural detail for induction, monitoring and post-procedural care as well as endpoint, or until a new protocol has similarly been provided and approved. Animals not undergoing seizure induction may continue to be used for other approved experiments until the current protocol expires.
- All members of the lab must complete all lessons of the AALAS Learning Library course, Common Compliance Issues, and pass.
- The addition of oral or systemic administration of d-serine to the protocol may not proceed until either the current protocol is amended, or a new protocol is written and approved. Also, enhanced monitoring criteria and endpoints must be included due to toxicity issues.
- All protocol personnel must be provided a copy of the protocol and review it with the principal investigator (PI). The PI must ensure all personnel are familiar with all protocol contents.
- Animal activities not approved by the FSU ACUC must not be referred to in publications and grant applications as ACUC-approved activities.

The above corrective actions ensure that appropriate procedures, experimental compounds, housing exemptions, and proper monitoring of animals are included in the protocol. The actions also ensure that laboratory personnel understand the protocol via review with the PI (and having a copy of the protocol) and understand the importance of compliance via online training.

Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate being notified of these matters and find no cause for further actions.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Director, Laboratory Animal Resources

A3854-N



FLORIDA STATE UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR RESEARCH

November 21, 2019

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7882

Dear Dr. Gopee,

Florida State University (FSU) [D16-00491, A3854-01] provides notification of a reportable event in accordance with Policy IV.F.3.

An Adverse Event Report filed on July 10, 2019, related to animal deaths associated with a temporal lobe epilepsy project initiated a preliminary investigation by FSU veterinary staff. On July 31, 2019, the FSU Animal Care and Use Committee (ACUC) was informed that the animal deaths appeared to be associated with the administration of a drug via an unapproved route. Pursuant to FSU ACUC procedures, a subcommittee of ACUC voting members was appointed to investigate the concern. The subcommittee reviewed lab records for the previous year in conjunction with staff interviews and review of laboratory operating procedures. The subcommittee concluded that there had been protocol drift resulting in non-compliance related to the administration of drugs, lack of documentation of post-procedural care and failure to obtain an exemption for individual animal housing.

At a convened meeting on September 25, 2019, the investigative subcommittee recommended several actions. By unanimous vote of the quorum, the Committee accepted all of the subcommittee's recommendations, hereby listed below.

1. Animal activity involving seizure induction is suspended until such time as the current protocol has been amended and approved to accurately reflect all procedural detail for induction, monitoring, and post-procedural care as well as endpoints, or until such time as a new protocol has similarly been provided and approved. Animals not undergoing seizure induction may continue to be used for other approved experiments until the current protocol expires.
2. All members of the lab must complete all lessons of the AALAS Learning Library course, Common Compliance Issues, and pass with a score equal to or greater than 85%.
3. The addition of oral or systemic administration of d-serine to the protocol may not proceed until either the current protocol is amended or a new protocol is written

and either version approved. Enhanced monitoring criteria and endpoints must be included due to toxicity issues.

4. All protocol personnel (both current and future) must be provided a copy of the protocol and review it with the principal investigator. The principal investigator must ensure that all personnel are familiar with all protocol contents.
5. Animal activities not approved by the FSU ACUC must not be referred to in publications and grant applications as ACUC-approved activities.

The reportable event described above is related to activities supported by NINDS award R01NS097802.

Florida State University takes very seriously our commitment to animal care. We trust our response to this matter will eliminate future similar occurrences. Please contact Dr. William Hill, Laboratory Animal Resources Director and FSU Attending Veterinarian at wahill@fsu.edu or (b) (6) if you require additional information.

Sincerely,

(b) (6)

Gary K. Ostrander, PhD
Vice President for Research and
Institutional Official

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Tuesday, November 26, 2019 7:43 AM
To: 'William Hill'
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Florida State University (D16-00491, A3854-01) reportable incident notification

Thank you for this final report Dr. Hill. We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DABT, DACLAM
Director, Division of Policy and Education
Office of Laboratory Animal Welfare, NIH
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Bethesda, MD 20892-6910
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gopeenv@od.nih.gov

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From: William Hill <wahill@fsu.edu>
Sent: Monday, November 25, 2019 3:46 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Florida State University (D16-00491, A3854-01) reportable incident notification

Dr. Gopee,

Good afternoon. Please see attached. Please contact me directly if you have questions or concerns. Thank you.

William Allen Hill, DVM, MPH, DACLAM, CPIA
Director, Laboratory Animal Resources and
Attending Veterinarian
Florida State University
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(b) (4) Biomedical Research Facility
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Laboratory Animal Resources is dedicated to advancing the teaching and research missions of the University by maintaining exemplary standards of animal care and providing exceptional support in the use of laboratory animals.