



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

August 13, 2019

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

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 August 6, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Florida State University. According to the information provided, OLAW understands that Prairie voles were subjected to unapproved surgical procedures.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) directing the Principal Investigator to stop the unapproved activities, to submit standard operating procedures for all surgical procedures, to submit revised post-operative monitoring forms, to have all staff undertake retraining with the veterinarian, and to provide staff a copy of the protocol and ensure staff understands the content.

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. Note that the NIH grant is not to be charged for any unauthorized procedures. Also note that most journals will not publish data based on animal activities that had not been approved by the IACUC. 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  
Robert Gibbens, D.V.M., USDA-APHIS-AC



FLORIDA STATE UNIVERSITY  
OFFICE OF THE VICE PRESIDENT FOR RESEARCH

August 6, 2019

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare  
National Institute 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.

On April 12, 2019, FSU veterinary personnel notified the Animal Care and Use Committee (ACUC) of a concern involving multiple Prairie voles. Specifically, voles had undergone an unapproved surgical procedure to subcutaneously implant estradiol pellets. Pursuant to FSU ACUC procedures, a subcommittee of ACUC voting members was appointed to investigate the concern. At the request of the ACUC, the Principal Investigator voluntarily halted all surgical activity until the ACUC completed its investigation and issued a written summary of allegations, findings, determinations, and corrective actions.

Based on a preponderance of the evidence, the investigative subcommittee determined a non-compliance incident occurred and issued the following recommendations:

- The laboratory must develop and submit to the ACUC for approval Standard Operating Procedures for all surgical procedures, as well as revised post-operative monitoring forms
- All protocol personnel must attend a training sessions with the Attending Veterinarian or designee covering protocol procedures, post-operative care, recordkeeping, and adverse outcome reporting
- The Principal Investigator must ensure all protocol personnel are provided a copy of the approved Animal Use protocol and are familiar with all protocol contents

By unanimous vote of quorum, the ACUC accepted the recommendations of the investigative subcommittee. On July 23, 2019, the laboratory fulfilled all remediation requirements. The reportable event detailed above is related to activities supported by NIH award NIMH109450-01A1.

Dr. Neera V. Gopee

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August 6, 2019

Florida State University takes very seriously our commitment to animal care. We trust our decisive response to this matter will eliminate future similar occurrences. Please contact me or Dr. William Hill, Laboratory Animal Resources Director and Attending Veterinarian if you require additional information.

Sincerely,

(b) (6)

A large rectangular area of the document is redacted with a solid grey box, obscuring the signature and any handwritten notes.

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

## Wolff, Axel (NIH/OD) [E]

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**From:** Gopee, Neera (NIH/OD) [E]  
**Sent:** Friday, August 9, 2019 3:43 AM  
**To:** William Hill  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD); Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]  
**Subject:** FW: Florida State University (D16-00491, A3854-01) reportable incident notification  
**Attachments:** SKMBizhub\_C19080808390.pdf

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  
6700B Rockledge Drive  
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**From:** William Hill <wahill@fsu.edu>  
**Sent:** Thursday, August 08, 2019 2:09 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  
107 Chieftan Way  
(b) (4) Biomedical Research Facility  
Tallahassee, Florida 32306-4341  
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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.*