



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

September 10, 2019

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

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 September 3, 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 on June 26, 2019 your ACUC was informed that the surgical records for four mice that underwent spinal cord injury surgeries on June 20, 2019 did not contain notation of post-surgical administration of protocol-required analgesics. Additional review of records for an additional 20 animals that underwent surgeries between March 2017 and March 2019 revealed that post-operative care was inadequate and inconsistent with the protocol. The ACUC voted to suspend this protocol on July 31, 2019. It is understood that this animal activity was funded by NSF grant 1661727. It was also determined that unapproved injection of tumor cells took place on a separate protocol in the same laboratory. The funding source for this second protocol was not stated. The ACUC determined to apply the same corrective and preventive measures for this protocol, including protocol suspension effective for this protocol on August 28, 2019.

Other corrective and preventive measures included in-person IACUC training for the PI at a course approved by the FSU IACUC. All other protocol personnel must complete AALAS learning module Common Compliance Issues. After completion of training the PI must submit a revised protocol. IACUC oversight of further surgical procedures will last no less than six months from the resumption of activities.

OLAW believes that the corrective and preventative measures put in place by Florida State University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this unfortunate incident and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Director, Laboratory Animal Resources
NSF Animal Welfare Officer



FLORIDA STATE UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR RESEARCH

September 3, 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 reportable events in accordance with Policy, IV.F.3.

On June 26, 2019, the FSU Animal Care and Use Committee (ACUC) was informed that surgical records for four mice that underwent spinal cord injury surgeries on June 20, 2019, did not contain notation of post-surgical administration of analgesics as described in the approved protocol. Pursuant to FSU ACUC procedures, a subcommittee of ACUC voting members was appointed to investigate the concern. Briefly, upon review of additional laboratory records for 20 animals that underwent spinal cord injury surgeries between March 2017 and March 2019, the investigative subcommittee found that post-operative care provided to animals was inadequate and inconsistent with approved protocol procedures.

Based on a preponderance of the evidence, the investigative subcommittee determined serious and continuing noncompliance occurred and recommended suspension of all protocol 1705 animal activities. Additionally the subcommittee recommended the following conditions be met before consideration of a new protocol submission describing animal activity performed under the protocol.

- The Principal Investigator must complete face-to-face, in-person training relative to IACUC processes and procedures and federal regulations regarding animal care and use offered by IACUC 101, SCAW, or another equivalent entity approved by the FSU ACUC.
- All other protocol personnel must complete the AALAS learning module Common Compliance Issues.
- Upon completion of the aforementioned training, the Principal Investigator must submit a revised protocol including Standard Operating Procedures with checklists outlining all surgical procedures, post-operative pain management, and care of animals as well as end point criteria.

Dr. Neera Gopee
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- Prior to resuming surgical activities, the ACUC must be notified in order that a representative from the committee may observe surgical procedures and post-operative care of animals. Oversight of surgical procedures by ACUC members will last no less than a period of 6 months from the time of resumption of activities.

At a convened meeting on July 31, 2019, and by unanimous vote of quorum, the ACUC accepted the full recommendations of the investigative subcommittee. The reportable event detailed above is related to activities supported by NSF award 1661727.

Following suspension of protocol 1705, the ACUC initiated an investigation into other animal activities performed by the same laboratory. Investigation procedures followed FSU ACUC procedures, including appointment of an investigative subcommittee. The subcommittee determined multiple animals used pursuant to protocol 1721 had received unapproved injections of tumor cells. The subcommittee recommended suspension of all animal activities conducted pursuant to protocol 1721 due to lack of Principle Investigator oversight. Additionally, the subcommittee recommended that the training conditions outlined to resume activity under protocol 1705 be satisfied before reactivation of protocol 1721 or consideration of any other protocol submission from the Principal Investigator. At a convened meeting on August 28, 2019, and by unanimous vote of quorum, the ACUC accepted the full recommendations of the investigative subcommittee.

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 Attending Veterinarian at wahill@fsu.edu or (b) (6) if you require additional information.

Sincerely,

(b) (6)

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 04, 2019 3:16 PM
To: William Hill; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Florida State University (D16-00491, A3854-01) reportable incident notification

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: William Hill [mailto:wahill@fsu.edu]
Sent: Wednesday, September 04, 2019 2:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@aaalac.org
Subject: Florida State University (D16-00491, A3854-01) reportable incident notification

Good afternoon. Please see attached. Thank you.

William Allen Hill, DVM, MPH, DACLAM, CPIA
Director, Laboratory Animal Resources and
Attending Veterinarian
Florida State University
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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.