



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

March 19, 2019

Re: Animal Welfare Assurance
A3011-01 [OLAW Case 1M]

Dr. Richard J. Reeder
Vice President for Research
State University of New York-Stony Brook
(b) (4) Melville Library
Stony Brook, NY 11794-3368

Dear Dr. Reeder,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 11, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at State University of New York- Stony Brook. According to the information provided, OLAW understands that specific aspects of a mouse study had not been approved in the protocol. The unapproved activity involved special housing and feeding activities.

The corrective action consisted of stopping the activity and transferring the mice to a different investigator working on a similar protocol. A new protocol was submitted and approved by the Institutional Animal Care and Use Committee and the content was discussed by the senior laboratory staff. The Principal Investigator (PI) will make the approved protocol available to staff, review details during weekly laboratory meetings, and ensure that only approved procedures are conducted. The PI and laboratory staff will be involved with any protocol changes and the annual renewal.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Assistant Director for Research Compliance



Stony Brook University

The State University of New York

March 11, 2019

Brent Morse, D.V.M.
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 9782
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Assurance # A3011-01; D16-00006

Dear Dr. Morse;

Enclosed please find an event that Stony Brook University has deemed reportable to your office in accordance with PHS Policy, IV.F.3.

Please contact [REDACTED] (b) (6) should you have any questions, or require additional information.

Sincerely,

[REDACTED] (b) (6)

Richard J. Reeder, PhD
Vice President for Research and Institutional Official

Xc: Stella Tsirka, PhD, IACUC Chair

[REDACTED] (b) (6)



Stony Brook University

**OLAW Reportable Event
[per PHS Policy at Section IV.F.3]
Animal Welfare Assurance # D-16-00006(A3011-01)**

Type of Report:

- ☐ Follow-up to prior report dated
- ☐ First report, with intent to follow-up with OLAW
- ☒ First and final report to OLAW 3.11.19

IACUC # or Pls lab: LR Lab, IACUC # 241318

Species: Mouse

Description of reportable incident:

A member of The Division of Laboratory Animal Research (DLAR) was contacted by the research staff of this PI to come into their lab and assist with the setup of sipper tubes. The DLAR staff member met with the lab member, and at that time noted that a procedure was being done on the mice that the lab did not have approval for. Upon further review of the details of the experiments and the description of the procedures in the approved IACUC protocol, it became clear to the PI that elements of the experiment had been inadvertently left out of the protocol. They immediately stopped the experiment. In summary, the investigators were approved to insert small cannulas into the basal lateral amygdala to allow focal, light activation of recombinant light sensitive ion channels. However they were not approved for the camera mounting hardware that had been installed, and which required special housing (removal of wire bar lid, feeding on cage floor and administering gel instead of water bottle). In order to use the animals with the optical devices already implanted, rather than euthanize them, they transferred the mice to the protocol of another PI whose lab has a very similar experimental protocol.

Corrective Actions:

The investigators immediately took responsibility for the oversight that resulted in this violation. They responded with a detailed explanation, apology and assurances that all future work will be properly supervised. In addition, they submitted a Full new application/protocol

that correctly detailed all the work that is being done. That submission was reviewed by the convened IACUC committee and approved on March 11th, 2019.

As a correction action plan, the PI has engaged all senior lab members in a process of detailed review of the approved IACUC protocol with the added details for the experiment in question that the PI missed.

Going forward, the PI has pledged to continue to (a) post and circulate the approved protocol for all lab members to review; (b) include discussions of details of the protocol at weekly lab data sub-group meetings. Currently, at these meetings, each lab member presents updates on their past week and coming week experiments. The updates include procedures that don't work and reporting of general issues regarding animals. The PI has extended this reporting to include discussion of how any new experiment proposed might deviate from procedures described, reviewed and approved in the protocol. This will allow a near constant evaluation of whether an experimental protocol is covered, or might require an amendment/modification before proceeding. (c) The lab members have been re-educated to always engage the PI in drafting and editing the protocol prior to, and again after review by the IACUC. (d) Finally, the PI plans to engage the entire lab in the annual renewals to ensure that any small variations that might improve the use of animals are incorporated.

Form completed by:

(b) (6)



Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 18, 2019 7:14 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable Event and CAPA plan from Stony Brook University

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Friday, March 15, 2019 2:29 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Richard Reeder <richard.j.reeder@stonybrook.edu>; Styliani-Anna Tsirka <styliani-anna.tsirka@stonybrook.edu>; (b) (6)
(b) (6) OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable Event and CAPA plan from Stony Brook University

Dear Dr. Morse,

- **Reportable Event From Stony Brook University**
- **Assurance #A3011-01; D16-00006**

As required by OLAW, attached below is a signed cover letter from our IO and a reportable event.

The event does not involve a USDA covered species.

A corrective action was implemented upon discovery of the event and the PI made the necessary changes to the protocol.

These changes were reviewed and accepted at the February 19, 2019 IACUC meeting. Finally, the PI has implemented some further corrective actions to prevent a future occurrence.

If you have any questions please feel free to contact me at any time.

Regards,

(b) (6)

(b) (6)