



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

July 25, 2019

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

Dr. Richard 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 July 22, 2019 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Stony Brook University. This letter responds to one of those incidents. According to the information provided, OLAW understands that breeding of mice was occurring on a protocol that did not include approval for breeding, only purchasing, of mice. It was not noted if this activity was funded by the PHS or NSF.

Corrective actions included the immediate cessation of breeding and the euthanasia of both the existing and anticipated litter. The PI assured that all future work would be properly supervised and that mice would only be purchased for the remainder of 2019. If breeding becomes necessary, the PI will submit a protocol amendment and will request training for his lab staff.

OLAW appreciates the prompt consideration of this matter by Stony Brook University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. Please include PHS/NSF funding information in future reports. We appreciate being informed of this matter 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



Stony Brook University

The State University of New York

July 22, 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 two events that Stony Brook University has deemed reportable to your office in accordance with PHS Policy, IV.F.3.

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

Sincerely,

(b) (6)

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

Xc: Stella Tsirka, PhD, IACUC Chair

(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 7.15.19

IACUC # or PIs lab: SP Lab, IACUC # 105527

Species: Mouse

Description of reportable incident:

A member of The Division of Laboratory Animal Research (DLAR) alerted us to activity by the research staff of this PI that the lab did not have approval for. The PI staff was breeding animals but the approved protocol only allows for purchasing of animals. All breeding activity was immediately stopped. The PI was instructed to humanely euthanize both the existing and the anticipated litter, and was told that the female animal could not be used for breeding until an amendment was submitted and approved.

Corrective Actions: As a corrective action plan the PI accepted full responsibility for the violation and the lack of oversight that resulted in the breeding. The PI responded with a detailed explanation, apology and assurances that all future work will be properly supervised. They have halted all breeding on the protocol and have agreed only to purchasing mice for the remainder of 2019. If breeding becomes necessary in the future the PI now understands that an amendment must be submitted, reviewed and approved by the IACUC. In addition, if future breeding is necessary, the PI will personally request training from the laboratory animal facility and will personally submit any necessary amendments to prevent such a failure of communication between the lab staff and the PI.

Form completed by:

(b) (6)



Ward, Joan (NIH/OD) [E]

Subject: FW: Two Reportable Events and CAPA from Stony Brook University

From: Ward, Joan (NIH/OD) [E]

Sent: Wednesday, July 24, 2019 6:18 AM

To: (b) (6) Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>

Subject: RE: Two Reportable Events and CAPA from Stony Brook University

Thank you (b) (6) for these two reports. Dr. Morse will respond soon.

Regards,
Joan

From: (b) (6)

Sent: Tuesday, July 23, 2019 4:26 PM

To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>

Subject: Two Reportable Events and CAPA from Stony Brook University

Dear Dr. Morse,

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

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

The events do not involve a USDA covered species.

Corrective actions were implemented upon discovery of the events. Both PI's plans include corrective actions to prevent a future occurrence.

These events and corrective plans were reviewed and accepted at a fully convened meeting of the IACUC.

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

Regards,

(b) (6)

(b) (6)