



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 1O]

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 a "collaborator" injected HCT116 cells into mice that were purchased for a different protocol. The "collaborator" was not approved to work with animals on either protocol. It was not noted if this activity was funded by the PHS or NSF.

Corrective actions included transferring the mice to the protocol that allowed the injection and adding the collaborator to the other protocol. All personnel involved were counseled and educated and are once again aware what is approved on each of the protocols.

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

**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:** YH Lab, IACUC # 1201052 and 609817

**Species:** Mouse

**Description of reportable incident:**

There was a mix-up in the two approved protocols cited above, that was reported to us by the PI, and as a result an unapproved person was working on the protocol.

The PI is approved for xenografts on both protocols. Mice were ordered on both protocols on 5/23/2019. The mice on protocol 1201052 arrived on 5/29/2019, and one of the researchers approved on protocol 609817 thought the mice were for their protocol and communicated to a "collaborator" that their mice had arrived. On the evening of 5/30/2019 the "collaborator" injected 12 of the 24 mice on protocol 1201052 with HCT116 cells. This cell line is only approved on protocol 608917. In addition, the "collaborator" was not approved on either protocol. Upon learning of the mix-up the PI transferred the 12 mice that had been injected onto protocol 608917 and added the collaborator to protocol 1201052.

**Corrective Actions:**

The investigator took responsibility for this event and self-reported. All personnel involved have been educated as to proper procedures when using mice and how to avoid future problems. Moreover all personnel on the two protocols have been made aware, once again, what is approved on each of the protocols. Both the researcher and the "collaborator" were also educated that they are required to be approved on a protocol before they can touch or experiment with live mice on any protocol.

**Form completed by:**

(b) (6)





**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)

**Ward, Joan (NIH/OD) [E]**

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**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)