



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 3, 2019

Re: Animal Welfare Assurance  
#A3260-01 (OLAW Case V)

Dr. Heidi Aronin  
Senior Vice President and  
Chief Administrative Officer  
SUNY Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Ms. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 21, 2019 letter reporting an adverse event within the animal care and use program at the SUNY Downstate Medical Center. Your letter supplements the information provided to this office in a December 31, 2018 initial telephone report and subsequent phone conversations. According to the information provided, OLAW understands that on November 1, 2018 a macaque died under anesthesia while undergoing a protocol-approved surgical procedure to repair an existing cranial implant. The death was most likely due to hypovolemic shock or cerebral ischemia. This activity was funded by the National Science Foundation (NSF).

Corrective and preventive actions include the surgical team meeting with the veterinary staff prior to surgeries to review all aspects of the planned procedure and potential complications. Additionally, the laboratory members will meet to review in detail the steps of the procedure, each person's roles and responsibilities, all associated surgical approaches and techniques, and important anatomic landmarks.

OLAW appreciates the consideration of this matter by the SUNY Downstate Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken regarding this incident. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Contact  
NSF Animal Welfare Officer  
Dr. Robert M. Gibbens, USDA, APHIS, AC



SUNY  
**DOWNSTATE**  
Medical Center

University Hospital of Brooklyn  
College of Medicine  
School of Graduate Studies  
School of Public Health  
College of Nursing  
College of Health Related Professions

**Institutional Animal Care and Use Committee**

June 21, 2019

Director, Division of Compliance Oversight  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Animal Welfare Assurance Number: D16-00167(A3260-01)

Dear Dr. Morse,

I'm writing to advise you of an adverse event associated with a National Science Foundation funded study. On November 1, 2018 an animal underwent a surgical procedure to repair an existing cranial implant as described in the approved protocol. During the course of the procedure, the animal experienced an unanticipated surgical complication and expired, most likely due to hypovolemic shock or cerebral ischemia. The animal did not experience pain or distress because of this event. Prior to future surgeries, the surgical team will meet with the veterinary staff to review all aspects of the planned procedure and potential complications. Additionally, the laboratory members will meet to review in detail the steps of the procedure, each person's roles and responsibilities, all associated surgical approaches and techniques, and important anatomic landmarks. Please let us know if you need additional information on this matter.

Best,

(b) (6)

Heidi J. Aronin, MPA  
Institutional Official

**Morse, Brent (NIH/OD) [E]**

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**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Monday, July 01, 2019 8:36 AM  
**To:** Julie Sharp  
**Cc:** Heidi Aronin; (b) (6)  
**Subject:** RE: D16-00167 - Adverse Event Report

Thank you for providing this final report Dr. Sharp. 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

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**From:** Julie Sharp [mailto:Julie.Sharp@downstate.edu]  
**Sent:** Tuesday, June 25, 2019 4:23 PM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** Heidi Aronin <Heidi.Aronin@downstate.edu>; (b) (6)  
**Subject:** D16-00167 - Adverse Event Report

Dear Dr. Morse,

Attached is the written report from the adverse event of November 1, 2018 that we've previously discussed by phone. Please let me know if you have any questions or need additional information.

Best,  
Julie

Julie M. Sharp, DVM, CPIA, DACLAM  
Director, Office of Animal Welfare  
Office of Research Administration – IACUC

SUNY - Downstate Medical Center  
450 Clarkson Ave., MSC 112  
Brooklyn, NY 11203-2098  
Office: (b) (6)  
Fax: (b) (6)  
<http://research.downstate.edu/iacuc/iacuc.html>





## Initial Report of Noncompliance

By: *BSM*Date: *12/31/18*Time: *1:00*Name of Person reporting: *Julie Sharp, DVM*Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *SUNY-Downstate*Assurance number: *A3260*Did incident involve PHS funded activity? *NSF*

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened? *Animal died during head - cap surgery. Unexpected blood loss. Died w/o anesthetic recovery.*Species involved: *Marmoset*Personnel involved: *Researcher*Dates and times: *11/1/18*Animal deaths: *Yes*

Projected plan and schedule for correction/prevention (if known):

*NSF grant #'s to be provided.*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_



Division of Compliance Oversight

Record of Call for Case # A3260-V

Date & Time	Message	Initials
4/10/19 3:40	Dr. Sharp called w/ update. NSF grant # 1734887. No protocol noncompliance. Adverse event, animal never regained consciousness. Surgical team will meet w/ Vets to plan any future surgeries.	Bum
6/21/19 12:45	Spoke w/ Dr. Sharp. Final letter to be sent to I.O. today.	Bum