



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) 480-3387

November 3, 2021

Re: Animal Welfare Assurance  
#A3260-01 (OLAW Case Z]

Ms. 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 October 21, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the State University of New York Downstate Medical Center - Brooklyn. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the SUNY Downstate Medical Center Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states the IACUC office informed a Principal Investigator (PI) of his low animal number balance several times in September. On October 1, 2021, the animal balance was negative, and the PI submitted an amendment to include an additional 500 mice. The amendment was approved on October 6, 2021.

Per the report, no animal welfare issues, or adverse events were identified due to the noncompliance. The IACUC Office recommended the PI schedule a consultation with the Attending Veterinarian to reassess animal numbers for the next three-year period as the corrective action.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the State University of New York Downstate Medical Center - Brooklyn has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.

Tubbs -S

Digitally signed by Jacquelyn T.  
Tubbs -S  
Date: 2021.11.03 14:59:36 -0400

Jacquelyn Tubbs, DVM, DACLAM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



**Institutional Animal Care and Use Committee**

October 21, 2021

Dr. Brent Morse, DVM, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

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

Dear Dr. Morse,

I am writing to inform you of a non-compliance associated with NIH grant number R01HL139582 whereby the protocol exceeded the number of animals approved by the IACUC.

The IACUC Office notified (b) (6) of his low animal balance on 9/15/2021, 9/20/2021, and 9/22/2021. On 10/1/2021, the animal balance was negative and (b) (6) submitted an amendment to include 500 additional mice. This amendment was approved on 10/06/2021 and the protocol became compliant once more.

No animal welfare issues or adverse events were found to have occurred due to the non-compliance. The IACUC Office recommended as corrective action that the Principal Investigator schedule a consultation with the Attending Veterinarian to re-evaluate protocol animal numbers for the next Three-year period to avoid future potential non-compliance.

Best,

(b) (6)

Heidi J. Aronin  
Institutional Official

*State University of New York Downstate Health Sciences University  
450 Clarkson Avenue, Brooklyn, NY 11203-2098*

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, October 27, 2021 7:35 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of Non-Compliance for Assurance # D16-00167(A3260-01)

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:** Tuesday, October 26, 2021 10:47 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Heidi Aronin <Heidi.Aronin@downstate.edu>; IACUC <IACUC@downstate.edu>  
**Subject:** Report of Non-Compliance for Assurance # D16-00167(A3260-01)

Dear Division of Compliance Oversight,

Please note that SUNY Downstate Health Sciences University is reporting the attached non-compliance issue. No initial report was done since the event occurred and was resolved within a week.

(b) (6)



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